> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under [28 U.S.C. § 2201] for a declaratory judgment that such patent is invalid or not infringed.

INTRODUCTION

In 1984, Congress enacted the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetics Act[2] to accelerate the introduction of generic drugs in order to moderate the ever-increasing cost of prescription medication in the United States. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670-74 (1990). A critical means for achieving this goal was to encourage the prompt resolution of disputes concerning the application of pharmaceutical patents to

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[2] Formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

proposed generic drug products *before* the launch of such drugs to eliminate patent uncertainty and to relieve generic companies of the need to risk potentially ruinous liability to determine whether their products infringe. To that end, Congress made the submission of an Abbreviated New Drug Application (an "ANDA") seeking regulatory approval to market a generic drug before the expiration of any such patent an "act of infringement" sufficient to support an immediate patent infringement lawsuit. 35 U.S.C. § 271(e)(2).

By 2003, Congress recognized that some pharmaceutical patentees refrained from bringing infringement lawsuits under § 271(e)(2) specifically to avoid resolving patent uncertainty and thereby to delay competition from generic drug companies. The ability of generic drug companies to forestall such delay by bringing declaratory judgment actions was in doubt because in non-ANDA cases the Federal Circuit had ruled that a plaintiff could seek a declaration of invalidity or non-infringement only by proving that it faced a reasonable apprehension of being sued for infringement. It was not at all clear that a generic company could make such a showing against a patentee that pursued a strategy of avoiding litigation. In response, Congress amended 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e) specifically to direct district courts to hear declaratory judgment actions by generic drug companies "to the extent consistent with the Constitution."

However, in this case the Federal Circuit ruled *as a matter of constitutional law* that jurisdiction to hear such actions exists *only* where the generic company can prove that it faces imminent suit for patent infringement. This Court has never adopted such a rule, which is inconsistent with this

Court's Article III jurisprudence, and several other circuits have rejected it.

The Federal Circuit's ruling eviscerates the 2003 amendments by precluding generic companies from pursuing declaratory judgment actions in precisely the situations where Congress sought to make them available, *i.e.*, where a pharmaceutical patentee can effectively extend the life of its patent by *delaying* suit for patent infringement. Moreover, by grounding its ruling in the Constitution, the Federal Circuit effectively has tied Congress' hands. Only this Court's review can remedy this untenable situation.

STATEMENT OF THE CASE

Teva's Abbreviated New Drug Application

Petitioner, Teva Pharmaceuticals USA, Inc. ("Teva"), develops and sells generic drugs. In July 2002, Teva submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to sell a generic version of the antidepressant sertraline. Respondent, Pfizer, Inc. ("Pfizer") sells sertraline under the trade name Zoloft®. Zoloft is a very successful drug, generating annual sales revenue in the billions of dollars. App. 8a.

As required by the Hatch-Waxman Amendments, Pfizer had identified patents that could reasonably be asserted against a generic sertraline product. *See* 21 U.S.C. § 355(b)(1). Two of those patents are pertinent here: U.S. Patent No. 4,356,518 (the "compound patent") claims sertraline itself and expires in June 2006; U.S. Patent No. 5,248,699 (the "polymorph patent") claims a particular crystalline form or "polymorph" of sertraline, and expires in 2010. Pfizer listed these patents in the FDA's *Approved*

Drug Products with Therapeutic Equivalence Evaluations, a publication generally referred to as the "Orange Book."[3]

When Teva filed its ANDA for sertraline in 2002, it certified (i) that it would not market its generic sertraline product until the expiration of the compound patent, and (ii) that the polymorph patent was invalid and/or would not be infringed by Teva's generic sertraline product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III) and (IV). The first certification guaranteed that the FDA would not approve Teva's ANDA before the expiration of the compound patent four years later. 21 U.S.C. § 355(j)(5)(B)(ii). The second certification constituted an act of infringement of the polymorph patent sufficient to support federal subject matter jurisdiction over a patent infringement action against the ANDA applicant. 35 U.S.C. § 271(e)(2); *see Eli Lilly*, 496 U.S. at 678.

If Pfizer had sued Teva for infringing the polymorph patent within 45 days after receiving the second certification, the FDA would have been precluded from approving Teva's ANDA until either the court had ruled the patent invalid or not infringed or 30 months had elapsed, whichever occurred first. 21 U.S.C. § 355(j)(5)(B)(iii). Of course, since the FDA in any event would not approve Teva's ANDA until the expiration of the composition patent more than 30 months after the filing of Teva's ANDA, this automatic stay of FDA approval would have provided nothing of value to Pfizer.

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[3] The contents of the Orange Book are available online at http://www.fda.gov/cder/ob/default.htm.

Pfizer's Infringement Claim Against IVAX

Pfizer did not sue Teva within 45 days. Its forbearance, however, did not reflect indifference to competition to its blockbuster drug. Pfizer had earlier brought suit for infringing the polymorph patent against another generic drug company, IVAX Pharmaceuticals, Inc. ("IVAX"), that had filed an ANDA to market generic sertraline. That case settled[4] and the interplay between that settlement and federal pharmaceutical law explains Pfizer's decision not to bring an immediate infringement action against Teva.

Since IVAX was the first generic company to file an ANDA for approval of a generic sertraline product challenging the polymorph patent, it had an expectation of a lucrative 180 day "exclusivity" period during which no other generic sertraline product could be approved by the FDA. 21 U.S.C. § 355(j)(5)(B)(iv). However, like Teva, IVAX did not challenge the compound patent in its ANDA, and therefore was not in a position to enjoy its six months of "exclusivity" until the expiration of the compound patent in 2006. If any other generic company obtained a court decision that the polymorph patent was invalid or not infringed, the 180 day exclusivity period would commence, whether or not IVAX was able to launch its generic sertraline product. *See Minnesota Mining & Mfg. Co. v. Barr Labs.*, 289 F.3d 775, 780 (Fed. Cir. 2002). If such a court decision occurred more than 180 days before the expiration of the compound patent, IVAX would effectively lose its

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[4] Under the terms of the settlement, IVAX entered into a non-exclusive royalty-bearing license of the polymorph patent to commence upon the expiration of the composition patent. App. 9a.

exclusivity. In that situation, when the compound patent expired, Pfizer would face price competition, not only from IVAX (for which it would receive royalty payments), but also from other generic companies. It was, therefore, in Pfizer's interest to avoid, if possible, any litigation with another generic drug company that might have the effect of triggering IVAX's exclusivity before the expiration of the compound patent.

The District Court Decision

Teva sued Pfizer in January 2003 for a declaration that the polymorph patent was invalid and not infringed.[5] Teva sought to be in a position to launch its generic sertraline product immediately upon the expiration of the compound patent. However, avoiding the delay attributable to IVAX's exclusivity was not Teva's only concern. Teva faced exposure to significant infringement liability even if it delayed launching its product until after the compound patent expired *and* IVAX's exclusivity period had run. Teva sought to obtain patent certainty before launching, just as Congress had sought to encourage when it enacted the Hatch-Waxman Amendments in 1984. *See Eli Lilly*, 496 U.S. at 676.

Hoping to avoid any resolution of the patent issues (and thereby avoid any risk of triggering IVAX's exclusivity), Pfizer moved to dismiss Teva's action for want of subject matter jurisdiction, claiming that there was no "actual controversy." The district court granted the motion, ruling that Teva had not established that it faced a "reasonable apprehension ... that it will face an infringement

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[5] The bases for federal jurisdiction was 28 U.S.C. §§ 1331, 1338(a), 2201.

suit," as the court found to be required by Federal Circuit precedent. App. 43a-46a.

The Federal Circuit Panel Decision

On appeal to the Federal Circuit, Teva argued that legislation enacted in 2003 required the district court to hear Teva's declaratory judgment action. Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Amendments")[6] specifically authorized Teva to bring a "civil action to obtain patent certainty" against "the owner [of a patent listed in the Orange Book] or holder [of a New Drug Application for the drug associated with such listed patent] ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the [ANDA] applicant seeks approval ...." 21 U.S.C. § 355(j)(5)(C)(i)(II). Congress further provided that district courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" in any such action. 35 U.S.C. § 271(e)(5). Teva argued that these amendments established subject matter jurisdiction so long as the underlying patent dispute was justiciable under Article III and that that its dispute with Pfizer was plainly justiciable under this Court's "case or controversy" jurisprudence.

A number of *amici curiae* also urged the Federal Circuit to reverse the dismissal of Teva's claim for declaratory relief. The Federal Trade Commission emphasized the "vital role" that declaratory judgment actions by generic companies play in bringing generic drugs quickly to market. The Commission argued that Teva had raised an "actual controversy" because the resolution of the patent

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[6] Pub. L. No. 108-173 (2003).

dispute between Teva and Pfizer affected the timing of FDA approval of Teva's ANDA and Teva therefore faced a redressable injury that potential infringers not subject to the pharmaceutical regulatory process do not face. Brief for *Amicus Curiae* Federal Trade Commission Supporting Appellant and Urging Reversal. AARP emphasized the importance of declaratory judgment actions in bringing generic drugs to market quickly to ameliorate the burdens of prescription drug costs on older Americans and on giving effect to Congress' direction that jurisdiction over such actions be exercised to the limits of Article III. Brief of AARP as *Amicus Curiae* in Support of Appellant.[7]

The Federal Circuit panel, in a 2-1 decision, rejected Teva's arguments and affirmed the dismissal. It ruled that Article III itself *requires* that a declaratory judgment plaintiff prove that the defendant's acts triggered a reasonable apprehension that the defendant will sue the plaintiff for patent infringement. App. 18a-21a. Moreover, the panel recast this "reasonable apprehension" test to require proof that the reasonably apprehended infringement suit be "imminent." App. 16a-17a.

The holding that the "reasonable apprehension of imminent suit" test is a constitutional rather than a prudential limitation on jurisdiction logically should have ended the matter. Nevertheless, the panel went on to rule that in enacting the Medicare Amendments, Congress intended to preserve that test as a jurisdictional limitation on declaratory

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[7] The Generic Pharmaceutical Association, a trade association of generic drug companies, also submitted an amicus brief in support of Teva's position.

judgment suits brought by ANDA applicants pursuant to those amendments. App. 21a-24a.

Judge Mayer dissented. He concluded that Article III does not require the "reasonable apprehension" test because the decisions of this Court, beginning with *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937), establish that a "case or controversy" under Article III exists whenever the plaintiff has suffered injury in fact for which it seeks "specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts," App. 31a (quoting *Calderon v. Ashmus*, 523 U.S. 740, 746 (1998) (quoting *Aetna*, 300 U.S. at 241)), and that Teva had presented such a case. Judge Mayer also concluded that Pfizer's act of listing the polymorph patent in the Orange Book, an act that represented to the world that that patent "likely precludes" a generic sertraline product, was sufficient to give rise to a reasonable apprehension of infringement litigation. App. 32a.

Denial of Rehearing and Rehearing En Banc

Teva petitioned for rehearing and rehearing en banc. Despite amicus submissions by the Federal Trade Commission and others urging rehearing, the Court denied the petition on April 4, 2005, with three judges dissenting. App. 48a-50a.

Judge Mayer did not supplement his panel dissent. The two other dissenters, Judges Gajarsa and Dyk, each filed dissenting opinions in which the other joined. Judge Gajarsa observed that this Court's decisions establish that Article III requires only a redressable injury in fact, traceable to defendant's conduct, *e.g.*, *Steel Co. v. Citizens for a Better*

Environment, 523 U.S. 83, 103-04 (1998), and that this constitutional "minimum" was satisfied here. App. 51a-57a.

Judge Dyk wrote that the Article III decisions of this Court "provided no support" for the Federal Circuit's view that only a "reasonable apprehension of imminent suit" can establish an actual controversy, and noted the inconsistency of the approach taken by the panel majority with rulings of other circuits. App. 60a-63a. He concluded that the Medicare Amendments were plain on their face in requiring district courts to hear declaratory judgment actions by ANDA applicants if Article III's minimum "case or controversy" standards were satisfied. App. 64a.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's ruling gravely undermines recent congressional efforts to accelerate the introduction of generic drugs and thereby ameliorate the staggering cost of prescription drugs in the United States. Both Congress and this Court have recognized that the prompt resolution of disputes involving the application of pharmaceutical patents to generic drugs is critical to the achievement of this goal. Congress amended the law in 2003 to authorize declaratory judgment actions by generic drug companies and thereby ensure that such companies would have the same opportunity to obtain prompt "patent certainty" that Congress gave pharmaceutical patentees in 1984.

The decision below effectively nullified those amendments. The court below not only denied declaratory relief in precisely the situations in which Congress sought to make such relief available, but also prevented Congress from ever providing such relief by grounding its ruling in the Constitution itself. It is difficult to imagine a more complete

frustration of congressional purpose in an area of vital importance to the nation's health care system. Accordingly, this case presents a "matter of special importance to the entire Nation," *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993).

The Federal Circuit reached its decision by finding Article III requirements that this Court has never imposed and that go well beyond what this Court has repeatedly identified as the essential characteristics of a justiciable "case or controversy." There is no question but that there would be jurisdiction to resolve the dispute between Teva and Pfizer in an infringement action brought by Pfizer, and this Court has emphasized that the identity of the party that initiates litigation to resolve a justiciable controversy is "immaterial" to the Article III question. *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). The Federal Circuit's decision also conflicts with decisions from other circuits and denies access to declaratory relief in situations in which both the Medicare Amendments and the Declaratory Judgment Act were intended to apply.

If the decision below is allowed to stand, no district court in the country will entertain declaratory judgment actions as Congress provided in the Medicare Amendments. Appeals from dismissals of declaratory judgment actions in patent cases are heard exclusively by the Federal Circuit, and every district court is bound by Federal Circuit precedent in such cases. Hence, only review by this Court can correct the misreading of its precedents and the frustration of national health care policy caused by the decision below.

I. The Decision Below Gravely Undermines Congressional Efforts to Reduce the Cost of Prescription Drugs.

The price of prescription drugs has grown dramatically in recent years, creating enormous burdens for patients (particularly the elderly), for employers who provide prescription drug benefits for their employees, and for the taxpayers who fund Medicare, Medicaid and other public health care programs. National expenditures for prescription drugs have risen from $12 billion in 1980 to $40 billion in 1990 to more than $170 billion in 2003.[8]

Generic drugs play a critical role in moderating this explosive growth in the cost of prescription drugs. A study cited by the Federal Trade Commission in 2002 reported that average drug prices declined 20% within two years of generic drug entry into the market and that the savings increase with the number of generic competitors.[9]

This Court has recognized that the Hatch-Waxman Amendments sought to accelerate the introduction of generic drugs. *Eli Lilly*, 496 U.S. at 670. Generic entry was often delayed because pharmaceutical patents prevented generic drug companies from even commencing their development efforts until those patents expired. This delay, coupled with a

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[8] Centers for Medicare & Medicaid Services, National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1980-2003 (available at http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp.)

[9] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 9 (2002) (available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.)

lengthy process of regulatory review, resulted in a *de facto* extension of the terms of pharmaceutical patents. *See id.*

The Hatch-Waxman Amendments addressed this problem in several ways. First, they required innovator companies to list in the Orange Book any patents that "could reasonably be asserted" against generic versions of the drugs to which they pertain. 21 U.S.C. § 355(b)(1). Second, they provided that the activities of companies to develop generic versions of patented products for purposes of seeking FDA approval would not constitute patent infringement. 35 U.S.C. § 271(e)(1). *See Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. ___, 125 S. Ct. 2372 (2005). Third, the Hatch-Waxman Amendments encouraged the resolution of patent disputes *before* generic companies launched their products (at risk of potentially ruinous liability) by (i) making the submission of an ANDA that seeks FDA approval before the expiration of an Orange Book patent (because the patent is invalid or not infringed) an act of infringement of such patent sufficient to support infringement litigation, and (ii) automatically delaying FDA approval of the generic drug by 30 months if the patentee commenced an infringement action within 45 days of receiving notice of this certification. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2).[10] This Court

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[10] The number of drugs as to which generic companies seek FDA approval before patent expiration is large and increasing. The FDA reports that since 1984 approximately 300 drugs have been the subject of ANDAs certifying that a patent said to cover the drug is invalid or not infringed, including more than 50 since March 2004. *See* http://www.fda.gov/cder/ogd/ppiv.htm. Since it is common for more than one generic drug company to file an ANDA with respect to a particular drug, these figures significantly understate the actual number of ANDAs filed containing such certifications.

recognized that without the ability to resolve infringement disputes promptly, the legislative scheme "will not work." *Eli Lilly*, 496 U.S. at 678.

By 2003, Congress recognized that the incentive of an automatic 30 month stay of FDA approval of a generic drug was often insufficient to prompt patentees to commence immediate infringement litigation against ANDA applicants that challenged their patents. As one supporter of the declaratory judgment provisions of the Medicare Amendments explained during the congressional debate over them:

> For example, the brand drug company might have several patents listed in the Food and Drug Administration's Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve. The suit on one patent would automatically stay approval of the generic application until the lawsuit is resolved or the 30 months elapses. Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement suit.
>
> .... Or when generic applicants are blocked by a first generic applicant's 180-day exclusivity,

> the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy) (App. 77a).[11] As lower courts had recognized, these delays could be avoided if generic companies could sue for a declaration of invalidity or non-infringement after the patentee failed to bring an infringement action within 45 days. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 (D.C. Cir. 1998); *Minnesota Mining*, 289 F.3d at 789-92 (Gajarsa, J., concurring).

The availability of this solution, however, was unclear in light of the Federal Circuit test for determining when a suit for a declaration of patent invalidity or non-infringement presented an "actual controversy." That test required "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004) (quoting *BP Chems., Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)). Since filing an ANDA certifying that an Orange Book patent is invalid or not infringed constitutes infringement as a matter of law, it was the "reasonable apprehension of suit" requirement that raised questions whether a declaratory

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[11] The complete colloquy is set forth at App. 71a-81a.

judgment remedy would be available. *See Mova*, 140 F.3d at 1073.

In enacting Title XI of the Medicare Amendments — entitled "Access to Affordable Pharmaceuticals" — Congress sought to resolve this uncertainty by (i) expressly granting generic companies the right to seek a declaration of invalidity or non-infringement when the patentee does not bring suit within 45 days of receiving the generic company's certification, 21 U.S.C. § 355(j)(5)(C)(i)(II), and (ii) directing district courts to exercise jurisdiction over such declaratory judgment actions "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5).

Congress plainly anticipated that this legislation would expand the ability of generic companies to bring declaratory judgment actions. ANDA applicants that could demonstrate a reasonable apprehension of suit could have brought declaratory judgment actions under existing Federal Circuit law without any further legislative authorization. Congress does not amend laws simply to preserve the legal status quo.[12] On the contrary, Congress expected that as a result of expanding declaratory judgment jurisdiction, patients would get quicker "access to affordable

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[12] Contrary to the Federal Circuit's conclusion, the Conference Committee Report does not reflect the intent of the conferees to apply the reasonable apprehension test whether or not the Constitution requires it. The report refers, consistent with the statutory language, to applying that test "to the extent required by Article III." *See* H.R. Conf. Rep. No. 108-391, at 836 (2003) (App. 82a-83a). Nor does the Report reflect any conclusion by Congress that that test is constitutionally required.

pharmaceuticals" and dramatic cost savings would be achieved.[13]

The Federal Circuit decision completely frustrates that congressional purpose. The court not only ruled that the Constitution *always* required satisfaction of the "reasonable apprehension" test, but also reformulated the test to require a reasonable apprehension of *imminent* infringement litigation. As noted above, Congress provided that ANDA applicants could bring declaratory judgment actions specifically to address situations in which the owners of Orange Book patents had a financial incentive to *delay* the commencement of infringement litigation. Thus, *by imposing an "imminence" requirement, the Federal Circuit guaranteed that there would be no declaratory judgment remedy in precisely this situation in which Congress intended to make such a remedy available.*

The "imminence" requirement also undermines one of the principal goals of the Declaratory Judgment Act itself: to provide a remedy for a potential defendant that is unable to obtain a binding determination whether its product infringes a patent. The paradigm of this type of case involves what this Court, quoting Learned Hand, called a "scarecrow" patent, *i.e.*, a weak patent on which the patentee does not

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[13] According to estimates prepared for Congress by the Congressional Budget Office, enactment of Title XI of the Medicare Amendments would result in cost savings of $600 million through FY 2013 and (along with Title I of the Medicare Amendments) in $7.2 billion in increased revenues. Letter from Douglas Holtz-Eakin, Director Congressional Budget Office to Hon. William M. Thomas, Chairman, House Committee on Ways and Means (Nov. 20, 2003) (available at http://cbo.gov/ftpdocs/48xx/doc4808/11-20-MedicareLetter.pdf).

bring suit but that scares off the potential infringer and its customers. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95-96 (1993) (citing *Bresnick v. United States Vitamin Corp.*, 139 F.2d 239, 242 (2d Cir. 1943) (L. Hand, J.)). In *Cardinal*, this Court noted that "[m]erely the desire to avoid the threat of a 'scarecrow' patent ... may ... be sufficient to establish jurisdiction under the Declaratory Judgment Act." *Id.* at 96.[14]

By definition, the victim of a "scarecrow" patent faces no likelihood of imminent infringement litigation. Yet the Federal Circuit's decision in this case would deny declaratory relief to the victims of such patents on constitutional grounds.

It is difficult to imagine a more complete undermining of important federal legislation than that brought about by the Federal Circuit's decision in this case. This Court should grant review to determine whether Article III genuinely requires such a result.

II. The Decision Below Purports to Resolve an Important Federal Question in a Manner that Conflicts with the Decisions of this Court and those of other Federal Circuit Courts.

The Medicare Amendments provide that district courts should exercise jurisdiction over declaratory judgment

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[14] Moreover, as Judge Hand said in another patent case, "[i]f a manufacturer fears that he will be charged to infringe, he can always inquire of the patentee, and if the answer is unsatisfactory, he can bring an action for a declaratory judgment. *The time has now passed when a patentee may sit by and refuse to show his hand.*" *Clair v. Kastar*, 148 F.2d 644, 646 (2d Cir. 1945) (emphasis added).

actions brought by generic drug companies in the circumstances presented here unless it is unconstitutional to do so. 35 U.S.C. § 271(e)(5). This Court has recognized Congress' authority to preclude the application of any merely prudential limitation on the subject matter jurisdiction of federal courts. *E.g.*, *Bennett v. Spear*, 520 U.S. 154, 162 (1997); *Warth v. Seldin*, 422 U.S. 490, 501 (1975).

This Court has ruled repeatedly that Article III's "irreducible constitutional minimum" is that the plaintiff "demonstrate that he has suffered 'injury in fact,' that the injury is 'fairly traceable' to the actions of the defendant, and that the injury will likely be redressed by a favorable decision." *E.g.*, *Bennett*, 520 U.S. at 162 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). In no case discussing this constitutional minimum has this Court required a "reasonable apprehension of imminent litigation."

In particular, the Court imposed no such requirement in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937), which upheld the constitutionality of the Declaratory Judgment Act against Article III challenge and established the framework for analyzing the applicability of Article III to declaratory judgment actions. In the words of Chief Justice Hughes, to fall within the "judicial Power" of Article III, the declaratory plaintiff's claim "must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of

facts." *Id.* at 241.[15] The insurance company plaintiff in *Aetna* sought a declaration of non-coverage and there is no hint in the Court's opinion that the insurer faced any threat of imminent litigation. The harm that the insurer invoked to justify declaratory relief was the prejudice to its ability to prove non-coverage through the death or disappearance of witnesses. *Id.* at 239.[16] *See also Asarco, Inc. v. Kadish*, 490 U.S. 605, 619 (1989) (articulating requirement for "case or controversy" in terms of the adversity of the parties and the existence of valuable legal rights that will be affected "to a specific and substantial degree by the decision of the question of law").

The Federal Circuit never attempted to ground its reasonable apprehension requirement in the Article III decisions of this Court. Rather, it read its own prior decisions as setting forth constitutional requirements, even though the Article III question was not squarely presented in any of those cases. This case is the first patent case reviewed by the Federal Circuit where Congress has directed the exercise of subject matter jurisdiction to the constitutional

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[15] This standard is clearly satisfied here. Teva seeks a judicial determination whether the specific pharmaceutical product described in exacting detail in its ANDA will infringe Pfizer's patent and whether the patent itself is valid. It has committed a statutory act of infringing that patent. There is nothing hypothetical about Teva's claim.

[16] In *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270 (1941), this Court extended the *Aetna* holding to permit an insurer to sue the party injured by its insured for a declaration of non-coverage. Although the injured party would have had the right to sue the insurer after obtaining a judgment against the insured, the injured party had not obtained such a judgment when the insurer brought its declaratory judgment action. Plainly, the insurer faced no *imminent* risk of coverage litigation.

limit. Accordingly, prior Federal Circuit precedent should not have precluded consideration of general principles of justiciability under Article III.

Teva plainly satisfied the "irreducible constitutional minimum" of injury, traceability and redressability, as the dissenting judges all recognized. Unless Teva can obtain a judicial determination whether its generic version of Zoloft infringes Pfizer's patent, it cannot trigger IVAX's exclusivity and thereby avoid delaying the launch of its generic product until at least six months after the composition patent expires. Nor can it avoid the risk of ruinous liability if it launches before such a determination. Those injuries are traceable to Pfizer's listing the polymorph patent in the Orange Book and they will be redressed by litigating the validity and infringement of that patent.[17]

Moreover, a concrete dispute exists between Teva and Pfizer because Teva has already committed a statutory act of infringement that gives rise to a dispute that is unquestionably justiciable at Pfizer's behest. "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the inquiry is the same in either case." *Maryland Cas.*, 312 U.S. at 273. Since an infringement suit brought by Pfizer within 45 days of Teva's certification with respect to the polymorph patent would have been justiciable, Teva's

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[17] The Federal Circuit minimized this injury as a mere "competitive disadvantage." App 26a. But a "competitive disadvantage" is precisely what the victims of "scarecrow" patents suffer, and this Court indicated in *Cardinal Chem.* that such harm may support a declaratory judgment action. Competitive injury is certainly "injury in fact" for Article III purposes. *See Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 151-52 (1970).

declaratory judgment action presenting the identical issues in a case involving the identical parties is justiciable as well. That Pfizer was not about to sue Teva does not affect this conclusion.

The "reasonable apprehension of imminent litigation" requirement is not only foreign to this Court's Article III jurisprudence; it also conflicts with the Article III decisions of other circuits. In *Sallen v. Corinthians Licenciamentos Ltda,* 273 F.3d 14 (1st Cir. 2001), the First Circuit expressly rejected the proposition that Article III requires a party seeking a declaration of his right to use the defendant's trademark in its internet domain name to demonstrate a reasonable likelihood that it will be sued for trademark infringement. The court noted that where an actual concrete controversy exists between the parties, it was unnecessary to prove that the defendant was reasonably likely to commence an infringement action. *Id.* at 25-26.

Similarly, in a recent unpublished decision, the Sixth Circuit also rejected the proposition that a reasonable apprehension of suit is categorically required to satisfy Article III. *Sankyo Corp. v. Nakamura Trading Corp.*, 2005 U.S. App. LEXIS 4339, at *9-*11 (6th Cir. Mar. 15, 2005). The court relied instead on the principles of justiciability set forth in the *Aetna Life* decision and the three-part test of injury, traceability and redressability.

Other circuits have formulated the "actual controversy" requirement for declaratory judgments in terms of whether the plaintiff faces a reasonable apprehension of future liability, not of imminent litigation. Indeed, that was the approach taken in patent decisions by other circuits before the establishment of the Federal Circuit. For example, in *Societe de Conditionnement en Aluminium v. Hunter*

Engineering Co., 655 F.2d 938 (9th Cir. 1981), the patentee specifically disclaimed any threat of infringement litigation, although, like Pfizer, it "refused to forbear from any future threats or litigation concerning" its patents. *Id.* at 941. Nonetheless, the court found an actual controversy sufficient to sustain a suit for a declaration of invalidity. Emphasizing that the constitutional standard was established by *Aetna*'s requirement of a "real and substantial controversy admitting of specific relief through a decree of a conclusive character," the court of appeals rejected any requirement of a threat of litigation. The critical fact was that the plaintiff had actually commenced arguably infringing activity as to which the patent presented a "Damoclean threat." *Id.* at 945.[18]

Because the Federal Circuit has departed from this Court's settled Article III principles and has announced a jurisdictional rule that conflicts with the decisions of other circuits, this Court should grant review.

III. The Decision Below will Impose an Unjustified and Unprecedented Limitation on Subject Matter Jurisdiction in Patent Cases throughout the Country that Congress will be Unable to Remedy.

The untenable situation created by the Federal Circuit's decision can only be remedied by this Court. The

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[18] *See also Starter Corp. v. Converse, Inc.*, 84 F.3d 592, 595 (2d Cir. 1996) (*per curiam*) (trademark case; "reasonable apprehension of liability"); *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555-56 (9th Cir. 1989) (copyright case; "reasonable apprehension ... of liability"); *Dewey & Alma Chem. Co. v. American Anode, Inc.*, 137 F.2d 68, 71 (3d Cir. 1943) (patent case; public notice by the patentee that certain practices constitute patent infringement supports declaratory judgment action).

Federal Circuit has exclusive jurisdiction over appeals in patent cases. 28 U.S.C. § 1295(a). Future litigants may seek en banc review from the Federal Circuit, but the refusal of that court to grant such review in this case, notwithstanding the cogency of the dissenting opinions and the urgings of the Federal Trade Commission, AARP and others as *amici curiae* in this case, lead one to infer that a majority of the Federal Circuit is committed to support the views of the panel in this case.

Moreover, by grounding its decision in the Constitution itself, the Federal Circuit has effectively prevented Congress from ever creating a declaratory judgment remedy in the circumstances presented here. Although the Federal Circuit inferred — incorrectly — that Congress intended to preserve the "reasonable apprehension" test, in the end Congress' intent does not matter if, as the Federal Circuit held, the test is constitutionally required. For this reason as well, the Court should grant review.

CONCLUSION

The Federal Circuit has grafted onto Article III a limitation on the subject matter jurisdiction of federal courts in declaratory judgment actions that this Court has never articulated and that other circuit courts have rejected outright.

For the reasons set forth herein, this Court should grant the petition for certiorari.

July 5, 2005

Respectfully submitted,

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APPENDIX

Appendix A — Opinion of the United States Court of Appeals for the Federal Circuit Filed January 21, 2005

United States Court of Appeals for the Federal Circuit

04-1186

TEVA PHARMACEUTICALS USA, INC.,
Plaintiff-Appellant,

v.

PFIZER, INC.,
Defendant-Appellee.

DECIDED: January 21, 2005

Before MAYER*, CLEVENGER, and SCHALL, Circuit Judges.

Opinion for the Court filed by Circuit Judge SCHALL. Dissenting opinion filed by Circuit Judge MAYER.

SCHALL, Circuit Judge.

Teva Pharmaceuticals USA, Inc. ("Teva") is a manufacturer of generic pharmaceuticals. In July of 2002, it filed an Abbreviated New Drug Application ("ANDA") pursuant to the provisions of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. In its ANDA, Teva sought the approval of the Food and Drug

* Judge Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

Administration ("FDA") to market its generic version of the drug sertraline hydrochloride. Sertraline hydrochloride is sold under the trade name Zoloft® by Pfizer, Inc. ("Pfizer"). Pfizer holds two patents relating to Zoloft®: U.S. Patent No. 4,536,518 (the '518 patent") and U.S. Patent No. 5,248,699 (the '699 patent").

When Teva filed its ANDA, it also filed what is called in Hatch-Waxman parlance a "paragraph III certification." In that certification, Teva stated that it would not market its generic drug until the '518 patent expires. Simultaneously, Teva filed a Hatch-Waxman "paragraph IV certification." In that certification, Teva stated that its generic drug did not infringe the '699 patent or, alternatively, that the '699 patent is invalid. The '699 patent expires after the '518 patent. Pursuant to the provisions of the Hatch-Waxman Amendments, Pfizer had forty-five days from the date it received notice of Teva's paragraph IV certification to sue Teva for infringement of the '699 patent, and during that period the statute barred Teva from filing a declaratory judgment action against Pfizer based upon its ANDA.

On January 24, 2003, after Pfizer failed to sue Teva within the forty-five-day period following Pfizer's receipt of notice of the paragraph IV certification, Teva filed a declaratory judgment action against Pfizer in the United States District Court for the District of Massachusetts. In its suit, Teva sought a determination that its generic drug did not infringe Pfizer's '699 patent or that the claims of the '699 patent were invalid. On December 8, 2003, the district court dismissed Teva's suit for lack of jurisdiction. It did so on the ground that Teva had failed to establish that an actual controversy existed between it and Pfizer, as required under

the Declaratory Judgment Act, 28 U.S.C. § 2201(a).[1] *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03- CV-10167-RGS, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

Teva now appeals the decision of the district court, claiming that the court erred as a matter of law in holding that there was no actual controversy between it and Pfizer. The court determined that Teva failed to show that Pfizer had taken actions giving rise to a reasonable apprehension on its part that Pfizer would sue it for infringement of the '699 patent. Having considered the arguments of the parties and several amici,[2] we see no error in the district court's ruling that Teva failed to establish that an actual controversy existed between it and Pfizer. We therefore affirm.

BACKGROUND

I.

A. *The Hatch-Waxman Amendments*

The Hatch-Waxman Amendments were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282). In the Amendments, Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2)

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[1] Unless otherwise indicated, all statutory references are to the 2003 version of the United States Code.

[2] Amicus Curiae Ivax Pharmaceuticals, Inc. submitted a brief in support of Pfizer urging affirmance. Amici Curiae the Federal Trade Commission, the Generic Pharmaceutical Association, and AARP submitted briefs in support of Teva urging reversal.

enabling competitors to bring low-cost, generic copies of those drugs to market. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

In order to speed up the approval process for generic drugs, the Amendments provide that a generic drug manufacturer may submit an ANDA for approval by the FDA, rather than a full New Drug Application ("NDA"). The ANDA may rely on the safety and efficacy studies previously submitted as part of the NDA by demonstrating the generic drug's bioequivalence with the previously approved drug product. *See* 21 U.S.C. § 355(j)(2)(A). Under 35 U.S.C. § 271(e)(1), it is not an act of patent infringement to engage in otherwise infringing acts necessary to prepare an ANDA. However, section 271(e)(2) provides that a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. 35 U.S.C. § 271(e)(2).

The Hatch-Waxman Amendments provide that NDA-holders must notify the FDA of all patents that "claim[ ] the drug for which the [NDA] applicant submitted the application ... and with respect to which a claim of patent infringement could reasonably be asserted ...." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). As part of the approval process, an ANDA applicant must make one of four certifications with respect to each patent listed in the Orange Book that claims the drug for which it is seeking approval: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is

submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.

Upon filing a paragraph IV certification as part of an ANDA, an applicant must give notice to the patentee and the NDA holder. The notice must include a detailed statement of the factual and legal bases for the opinion of the applicant that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B)(i). If the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic thirty-month "stay" goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires. 21 U.S.C. § 355(j)(5)(B)(iii). During this forty-five day period, the ANDA applicant is barred from filing a declaratory judgment action with respect to the patent at issue. *Id.* If no infringement action is filed during this forty-five day period, the FDA may approve the ANDA. *Id.*

The first ANDA applicant to file a paragraph IV certification enjoys a 180-day period of generic marketing exclusivity, during which the FDA may not approve a subsequent generic applicant's ANDA for the same drug product. 21 U.S.C. § 355(j)(5)(B)(iv). This provision provides an economic incentive for generic manufacturers to challenge the validity of listed patents and to "design around" patents to find alternative, non-infringing forms of patented drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 57 (July 2002). The 180-day exclusivity period typically begins on the date of the first commercial marketing of the drug by the first applicant. 21 U.S.C. § 355(j)(5)(B)(iv). The original Hatch-Waxman Amendments provided that the commencement of the 180-day exclusivity period could also be triggered by "the date of

a decision of a court ... holding the patent which is the subject of the certification to be invalid or not infringed."[3] *Id.*

B. *The 2003 Medicare Amendments*

Congress recently enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. The Act was signed into law on December 8, 2003. Title XI of the Act, entitled "Access to Affordable Pharmaceuticals," makes numerous changes in the Hatch-Waxman Amendments ("Medicare Amendments"). Among the changes is a provision for a "civil action to obtain patent certainty." 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). Pursuant to that provision, if the patentee or NDA-holder does not bring an infringement action within forty-five days after receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the applicant seeks approval. *Id.* In exchange, the ANDA applicant must make an offer of confidential access to its ANDA application so that the patentee or the NDA-holder can evaluate possible infringement. *Id.* The Medicare Amendments also provide that when the above circumstances are met, "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

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[3] As discussed in Part I.B., *infra,* in 2003 Congress enacted a more complex set of provisions relating to the 180-day exclusivity period. However, these new provisions do not apply in this case.

Congress also addressed the statutory scheme surrounding the 180-day market exclusivity period. Congress replaced the traditional court decision "trigger" with a more complex set of 180-day provisions. *See* 21 U.S.C. § 355(j)(5)(D) (Supp. 2004). However, the Medicare Amendments provide that these new forfeiture provisions are effective only with respect to those applications filed after December 8, 2003, for which no paragraph IV certification was made before December 8, 2003. Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1102(b), 117 Stat. at 2460. Thus, the new forfeiture provisions do not apply in this case.

II.

A. *The '518 and '699 Patents*

Pfizer's '518 patent, which expires on June 30, 2006, is directed to the chemical compound sertraline hydrochloride, which is useful for the treatment of mental depression and anxiety disorders.[4] Sertraline hydrochloride operates by interacting with serotonin, a chemical messenger that participates in the transmission of nerve impulses in the brain. Sertraline hydrochloride works to selectively block the uptake of serotonin by synaptic cells, thus reducing its re-entry into nerve cells and allowing serotonin levels between nerve cells in the brain to build up. Pfizer's '699 patent, which expires on September 28, 2010, is directed to a novel crystalline form of sertraline hydrochloride and to a method

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[4] The '518 patent was due to expire on December 30, 2005. However, the district court opinion explains that the FDA granted Pfizer a six-month pediatric exclusivity extension for the drug, pursuant to 21 U.S.C. § 355a, making June 30, 2006 the effective expiration date of the patent.

for preparing it.[5] The commercial embodiment of the '518 and '699 patents is the drug Zoloft®, a hugely successful drug which has been approved by the FDA for treatment of mood and anxiety disorders. According to Pfizer's Annual Report, Zoloft® generated revenues for the company in excess of $2 billion in 2002.

B. *Ivax Pharmaceuticals USA, Inc.'s ANDA filing relating to generic sertraline hydrochloride tablets*

Ivax Pharmaceuticals USA, Inc. ("Ivax") is a manufacturer of generic pharmaceuticals. In 1999, Ivax, then known as Zenith Goldline Pharmaceuticals, Inc., submitted an ANDA to the FDA for its generic version of sertraline hydrochloride. Since Pfizer had listed both the '518 and '699 patents in the Orange Book in connection with its NDA for Zoloft® tablets, Ivax was required to file a certification with respect to each patent as part of its ANDA. Ivax filed a paragraph III certification as to the '518 patent, stating that it was not seeking to market its generic version of sertraline hydrochloride prior to the expiration of the patent. Simultaneously, Ivax filed a paragraph IV certification as to the '699 patent, stating that its generic drug did not infringe the '699 patent, or alternatively, that the '699 patent was invalid.

Within forty-five days of its receipt of notice of Ivax's paragraph IV certification, Pfizer filed suit against Ivax for infringement of the '699 patent in the United States District Court for the District of New Jersey. *Pfizer, Inc. v.*

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[5] The district court's opinion recites that the '699 patent expires on September 29, 2010. We note that the electronic version of the Orange Book located on the FDA's website indicates that the '699 patent also was granted a six-month pediatric exclusivity extension.

Ivax Pharms. Inc., Nos. 00-408, 01-6007 (D.N.J. Jan. 1, 2000). In 2002, Pfizer and Ivax entered into a settlement agreement whereby Pfizer agreed to grant Ivax a royalty-bearing license on the '699 patent until its expiration in 2010. As a consequence of the agreement, Ivax is in a position to begin marketing its generic version of Zoloft® immediately upon expiration of the '518 patent on June 30, 2006.

As the first-filer of an ANDA for the generic version of Zoloft®, Ivax is entitled, under 21 U.S.C. § 355(j)(5)(B)(iv), to a 180-day generic market exclusivity period. This 180-day period will be triggered by the earlier of: (1) the first date of commercial marketing by the first generic applicant or (2) a "decision of a court ... holding the patent which is the subject of the [paragraph IV certification] to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(I-II).

C. *Teva's ANDA filing relating to generic sertraline hydrochloride tablets*

As noted, in July of 2002, Teva submitted an ANDA to the FDA for its generic version of Zoloft®. Like Ivax, Teva filed a paragraph III certification as to the '518 patent and a paragraph IV certification as to the '699 patent. Pfizer elected not to file suit against Teva for infringement of the '699 patent within the forty-five days following receipt of notice of Teva's paragraph IV certification, and to date no such suit has been filed.

D. *Teva's declaratory judgment action*

On January 24, 2003, Teva filed a declaratory judgment action in the United States District Court for the District of Massachusetts, seeking a declaration that its

generic version of Zoloft® does not infringe the '699 patent and a declaration that the '699 patent is invalid. On March 10, 2003, Pfizer moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of the absence of an actual controversy, as required by Article III of the Constitution. On December 8, 2003, the court granted Pfizer's motion to dismiss.

In addressing Pfizer's motion, the district court applied the two-part test formulated by this court to determine whether an actual controversy exists in a patent infringement suit. Under that test, there must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity. *See Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). The district court determined that Teva had satisfied the second prong of the test by filing its ANDA for generic sertraline hydrochloride. However, the court concluded that Teva had failed to satisfy the "reasonable apprehension" prong of the test.

Before the district court, Teva argued that Pfizer had created a reasonable apprehension of suit based upon the following considerations: (1) Pfizer had listed the '699 patent in the Orange Book; (2) Pfizer had refused to grant Teva a covenant not to sue; (3) Pfizer had aggressively asserted its patent rights against alleged infringers of other patents; (4) Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride; and (5) it was in Pfizer's self-interest to leave a "cloud of litigation" hanging over Teva.

With respect to the final consideration, Teva argued that Pfizer's settlement with Ivax gave Pfizer a vested interest in seeing Ivax preserve its 180-day exclusivity period.

The district court rejected Teva's contentions. First, the court noted that a blanket inference that, by listing a patent in the Orange Book, a patentee has declared its intention to sue any potential infringer would virtually eliminate the "reasonable apprehension" prong of the two-part test. Second, the court stated that there is nothing in the Federal Food, Drug, and Cosmetic Act that requires Pfizer to respond one way or another to Teva's request for a covenant not to sue. Third, the court found that Teva's subjective belief that it would be sued because Pfizer sued Ivax does not amount to an explicit threat indicating the imminence of suit. Finally, the court reasoned that, if anything, Pfizer's self-interest in protecting Ivax's exclusivity period makes the prospect of an immediate lawsuit against Teva even less likely.

Teva timely appealed the district court's decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2000).

ANALYSIS

I.

Our starting point is the Declaratory Judgment Act, 28 U.S.C. § 2201(a), the statute under which Teva filed its suit. The Act provides in relevant part as follows:

> In a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading,

> may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

The Act, which parallels Article III of the Constitution, "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). Generally, the presence of an "actual controversy," within the meaning of the Act, depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has substantial discretion to decline that jurisdiction. *Id.; see also Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995) (reaffirming that since its inception, "the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants"). As we summarized in *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991): "When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary."[6]

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[6] Because the district court dismissed Teva's suit for lack of jurisdiction, it did not reach the stage of exercising its jurisdiction to determine whether to entertain the suit.

This court has developed a two-part inquiry to determine whether there is an actual controversy in a suit requesting a declaration of patent non-infringement or invalidity. *EMC Corp.*, 89 F.3d at 811. The inquiry focuses on the conduct of both the patentee and the potential infringer. *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004). There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *Id.*; *Amana Refrigeration*, 172 F.3d at 855; *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

Teva contends on appeal that the district court erred in ruling that it had failed to demonstrate the existence of an actual controversy between it and Pfizer under our two-part test. Teva argues that it had reasonable, objective grounds to fear that Pfizer would bring an action for infringement of the '699 patent. Teva also argues that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the two-part test.

Our task is thus two-fold. First, we must determine whether the district court erred in holding that Teva failed to establish an actual controversy under Article III because it did not demonstrate that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent. Second, if we determine that the district court did not err in applying the law as it existed when it granted Pfizer's motion to dismiss, we must determine whether, as Teva argues, the effect of the Medicare Amendments was to establish jurisdiction in the district court over Teva's

declaratory judgment action. It is to the former question that we turn first.

II.

The district court's dismissal of Teva's declaratory judgment action for lack of jurisdiction presents a question of law that we review without deference. *Gen-Probe*, 359 F.3d at 1379. The parties agree that the second prong (present infringing activity) of our two-part test was met by the filing of Teva's paragraph IV certification with respect to the '699 patent. The case thus turns on the first prong (reasonable apprehension of suit). Teva argues that the district court erred when it determined that Pfizer had not created a reasonable apprehension that it would bring suit against Teva for infringement of the '699 patent.

As it did in the district court, Teva places primary significance on the fact that Pfizer listed the '699 patent in the Orange Book, thereby representing that the patent "could reasonably be asserted" against any generic sertraline product. Teva takes the position that the requirements of the reasonable apprehension prong of the two-part test are satisfied in virtually every case in which: (1) the NDA applicant has listed a patent in the Orange Book; (2) a generic manufacturer has submitted an ANDA which includes a paragraph IV certification for a drug covered by that patent; and (3) the NDA-holder or patentee has not brought an infringement suit within 45-days of receiving notice of the paragraph IV certification. Teva asserts that the only way a patentee in Pfizer's situation can defeat jurisdiction over an ANDA filer's declaratory judgment action is by affirmatively representing that it will not sue the filer.

Teva's reliance on Pfizer's listing of the '699 patent in the Orange Book is misplaced. The listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement. Without more, Pfizer's compliance with the Hatch-Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as Pfizer's patent enforcement intentions are concerned. The Orange Book is a listing of patents with respect to which claims of infringement "*could* be reasonably asserted ...." 21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however. *See Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004) ("More is needed than knowledge or notice of an adversely held patent.... The standard is objective, and focuses on whether the patentee manifested the intention to enforce the patent, and would be reasonably expected to enforce the patent against the declaratory plaintiff." (citations omitted)). We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.

In support of its contention that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent, Teva also points to Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue. We have stated that, "[w]hen the defendant's conduct, including its statements falls short of an express charge, one must consider the 'totality of the circumstances' in determining whether that conduct meets the first prong of the test." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987)). Although relevant to the analysis, neither of the factors upon which Teva relies is

dispositive in this case. *See BP Chems.*, 4 F.3d at 980 ("Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive." (internal citation omitted)); *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985) ("The prior patent litigation initiated by Semi-Alloys in 1975, against two other parties unconnected with Indium, was too remote to make Indium's apprehension of further litigation in 1982 reasonable ....").

In order for this case to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of *imminent* suit. Whether there is an "actual controversy" between parties having adverse legal interests depends upon whether the facts alleged show that there is a substantial controversy between the parties "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Casualty*, 312 U.S. at 273. This requirement of imminence reflects the Article III mandate that the injury in fact be "concrete," and "actual or imminent, not conjectural or hypothetical." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101 (1998). Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination, either of which would trigger Ivax's 180-day exclusivity period before Ivax is in a position to take advantage of the period by beginning commercial marketing of its generic sertraline drug upon expiration of the '518 patent. In any event, Pfizer need not sue Teva immediately, because Teva will not be able to receive FDA approval for its generic sertraline drug prior to the expiration of Ivax's 180-day exclusivity period, which will not begin until expiration of the '518 patent on June 30, 2006. Because Teva is unable

to demonstrate a reasonable apprehension of imminent suit on the part of Pfizer for infringement of the '699 patent, we cannot say that the district court erred in its application of the two-part test for determining whether an actual controversy exists in a patent infringement action.

III.

Teva also argues, however, that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the traditional two-part test. Although the Medicare Amendments were not in place when this case was before the district court, Congress provided that the provisions dealing with declaratory judgments would "apply to any proceeding ... that is pending on or after the date of the enactment of this Act regardless of the date on which the proceeding was commenced ...." Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1101(c)(1), 117 Stat. at 2456. Since the district court did not issue its opinion until December 8, 2003, the date the Medicare Amendments were enacted, the declaratory judgment provisions apply to this case.

The Medicare Amendments amended 35 U.S.C. § 271(e)(5) so that it reads as follows:

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection

> (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5) (Supp. 2004). Thus, the Amendments explicitly state that an ANDA filer who submits a paragraph IV certification with respect to a patent listed in the Orange Book may, "consistent with the Constitution," bring a declaratory judgment action with respect to the patent if the patent owner does not bring an infringement action within the statutory forty-five day period.[7]

Teva argues that, in view of the Medicare Amendments, its declaratory judgment suit presents a justiciable controversy under Article III. In making this argument, Teva starts from the premise that, in its words, the reasonable apprehension test serves "primarily prudential not constitutional concerns." (Br. for Teva at 52.) It then posits that, in the Medicare Amendments, Congress directed courts to exercise jurisdiction over declaratory judgment actions

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[7] Prior to the Medicare Amendments, there was no prohibition against an ANDA filer bringing a declaratory judgment action upon expiration of the forty-five day period.

such as this to the limits of Article III. Joined by Amicus Curiae the Federal Trade Commission ("FTC"), Teva urges that it has suffered injury independent of the threat of an infringement suit because the 180-day exclusivity period itself has major economic consequences in the case of a drug such as Zoloft®. Teva and the FTC argue that there is a clear connection between this injury and actions already taken by Pfizer. They contend that if Pfizer had not obtained the '699 patent and listed it in the Orange Book, settled its litigation with Ivax, declined to sue Teva, and refused Teva's request for a covenant not to sue, Teva would have the opportunity to gain access to the Zoloft® market during the 180-day period that will follow the expiration of the '518 patent.

As a preliminary matter, we do not agree with Teva that the reasonable apprehension of suit test represents a prudential rule rather than a constitutional requirement. In *EMC,* we squarely stated that we developed the two-part inquiry, of which the reasonable apprehension of suit test is one of the parts, "to determine whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity." 89 F.3d at 811. Teva, nevertheless, points to statements in several of our cases that it argues demonstrate that the test is, in fact, merely a prudential rule. *See Arrowhead,* 846 F.2d at 736 (stating that the two-part test is a "test often useful in evaluating complaints for declaratory judgments in patent cases"); *Fina Oil Chem. Co. v. Ewen,* 123 F.3d 1466, 1470 (Fed. Cir. 1997) ("Satisfaction of th[e] traditional two-part test is not ... a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement.");

Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1327 (Fed. Cir. 1998) (stating that the two-part test "contributes to policing the boundary between a constitutional controversy ... and 'a difference or dispute of a hypothetical or abstract character.'" (citation omitted)).

We do not think that the cases cited by Teva support the proposition that the reasonable apprehension of suit prong of our traditional two-part test is not a constitutional requirement. First, there is nothing in *Arrowhead* that supports that proposition. In *Arrowhead*, the court made clear that although the "actual controversy" test in suits requesting a declaration of patent noninfringement or invalidity has been stated in various ways depending on the particular facts at hand, "the test requires two core elements: (1) acts of defendant indicating an intent to enforce its patent; and (2) acts of plaintiff that might subject it or its customers to suit for patent infringement." *Arrowhead*, 846 F.2d at 737. At the same time, the statement from *Fina Oil* upon which Teva relies follows the court's recognition of the traditional two-part test. 123 F.3d at 1470. Under these circumstances, the statement at most suggests that the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met.[8] The statement in no way suggests that the traditional test does not address the Article III requirement of an actual case or controversy. Finally, the statement Teva quotes from *Hunter Douglas*, 153 F.3d at 1327, is really just another way of saying what we said in

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[8] In *Fina Oil*, the plaintiff sought a declaration that the inventors were properly named on the patent at issue in accordance with 35 U.S.C. § 116 (1994). The statement relied upon by Teva merely reflects that the precise formulation of the constitutional inquiry may vary depending on the facts of a given case.

EMC in expounding on the traditional two-part test: "This court's two-part test for declaratory judgment jurisdiction is designed to police the sometimes subtle line between cases in which the parties have adverse interests and cases in which those adverse interests have ripened into a dispute that may properly be deemed a controversy." 89 F.3d at 811. We would only add that we think this case presents just the sort of situation to which the *EMC* court alluded: Pfizer and Teva certainly have adverse interests. However, for a variety of reasons, their adverse interests have not ripened into an actual controversy.

Neither do we think that in the Medicare Amendments Congress intended to cause courts to alter the present test for determining whether an actual controversy exists in the Hatch-Waxman setting. The plain language of the amended statute—that courts shall have subject matter jurisdiction "to the extent consistent with the Constitution"—compels the conclusion that the Amendments were not meant to automatically bestow district court jurisdiction over actions such as Teva's. The legislative history of the Medicare Prescription Drug, Improvement, and Modernization Act supports this view. In the version of the legislation originally introduced in the Senate (S.1) in the 108th Congress, it was provided that the filing of a paragraph IV certification, and the failure of the patentee or NDA-holder to bring an infringement action within forty-five days after the receipt of notice,

> shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any

> patent that is the subject of the certification is invalid or not infringed.

Thus, as introduced, the legislation would have embodied the concurring opinion of Judge Gajarsa in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories,* 289 F.3d 775, 784 (Fed. Cir. 2002). Judge Gajarsa suggested that "the two acts of (1) a patentee listing a patent in the Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement." *Id.* at 791. However, after changes made in conference, the legislation that became law in the 108th Congress (H.R. 1) did not contain language automatically conferring subject matter jurisdiction in the district courts anytime a patent is listed in the Orange Book, a paragraph IV certification is filed with respect to the patent, and a patentee fails to bring suit for infringement within forty-five days of receipt of notice of the certification.

The Conference Committee Report on H.R. 1 states as follows:

> The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. See, e.g., Fina Oil and Chemical Co. v. Ewen, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002).[9] In any given case, the conferees expect a court may or may not find a

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[9] In *Vanguard Research*, while the patentee, Peat, had not made an express threat of litigation, it had (1) sought to enjoin the potential infringer, Vanguard, from production of the potentially infringing technology by filing suit against it on other grounds, (2) had written Vanguard a letter indicating that it no longer had the right to market the potentially infringing technology, and (3) had contacted the U.S. Army and Congress implying to them that Vanguard was using Peat's technology without Peat's permission. 304 F.3d at 1254. The court held that, based on the totality of circumstances, there was a reasonable apprehension of suit on the part of Vanguard.

> reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108-391 at 836 (2003).

We conclude that the plain language of the statute, as well as the legislative history, support the conclusion that Congress did not intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a "reasonable apprehension" of suit to establish Article III jurisdiction. Our traditional two-part test remains good law, and, as discussed above, we see no error in the district court's application of the test.

Teva nevertheless points to the statement in the Conference Committee Report that "the conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act." According to Teva, making the declaratory judgment inquiry turn on the imminence of an infringement suit renders the test subject to manipulation by the patentee, thereby undermining the goals of the Hatch-Waxman Amendments to resolve patent disputes promptly once the issues are joined by the listing of a patent in the Orange Book and the serving of a paragraph IV certification with respect to the patent. Teva argues that these goals are not being served in this case. Teva points out that in view of Pfizer's settlement with Ivax, it is in Pfizer's interest to not expose the '699 patent to litigation, because doing so would raise the possibility of a determination of invalidity or non-infringement, either of which might trigger the commencement of Ivax's 180-day exclusivity period before the expiration of the '518 patent, in which event the exclusivity period would be useless. Teva asserts, for example, that if Pfizer can avoid triggering Ivax's 180-day

exclusivity period until the expiration of the '518 patent, it can expect to enjoy six months selling Zoloft® with only one, royalty-paying generic competitor, Ivax. At the same time, if the '699 patent were held invalid or not infringed, it would mean that during the six-month period following the expiration of the '518 patent on June 30, 2006, Pfizer would face competition in the Zoloft® market, not only from Ivax, but from other generic manufacturers as well. These circumstances, Teva urges, constitute injury to it, because the effect of Pfizer's not bringing suit against Teva is to prevent Teva from challenging the '699 patent and thereby possibly opening the door to its being able to sell generic sertraline hydrochloride during the 180-day exclusivity period following expiration of the '518 patent.

With these same considerations in mind, the FTC states that "while in a 'classic patent declaratory judgment suit,' the ordinary two-part test is appropriate" (Br. for FTC at 17 (quoting *Fina Oil,* 123 F.3d at 1466)), a case such as the present one presents a different situation: "[I]n the Hatch-Waxman regime, a subsequent ANDA applicant may suffer direct legal injury and require judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents within the regulatory scheme." (Br. for FTC at 17-18.)

We are not persuaded by Teva's and the FTC's arguments. Whether an actual controversy exists between Teva and Pfizer turns on the reasonable apprehension of suit test, which remains in place under the Medicare Amendments, and we have concluded that, under that test, Teva has not established that an actual controversy exists between it and Pfizer. The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity

period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.

If it is the view of Congress that the 180-day exclusivity period for a first ANDA filer creates inequities, it can amend the Hatch-Waxman Amendments accordingly. Until it does so, however, we must apply the statutory scheme as written. *See Reid v. Dep't of Commerce*, 793 F.2d 277, 284 (Fed. Cir. 1986) ("'The remedy for any dissatisfaction with the results in a particular case lies with Congress' and not this court, 'Congress may amend the statute; we may not.'")(quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 576 (1982)). Thus, it is not for us to address any perceived inequities in the statutory scheme by eliminating the reasonable apprehension of suit test in Hatch-Waxman cases. That is what we would have to do in order to rule in favor of Teva in this case. That is because, in order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage vis-a-vis Ivax. Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

CONCLUSION

For the foregoing reasons, we agree with the district court that Teva failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a). We therefore affirm the court's dismissal of Teva's declaratory judgment suit for lack of jurisdiction.

AFFIRMED

MAYER, Circuit Judge*, dissenting.

Because the filing of a New Drug Application (NDA) and subsequent listing of a pharmaceutical patent in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") is conduct giving rise to a reasonable apprehension that an Abbreviated New Drug Application (ANDA) filer and declaratory judgment plaintiff will face a patent infringement suit, I respectfully dissent.

I.

Our traditional two-part test to determine whether an actual controversy exists in a patent infringement suit requires that "(1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the patentee has created in the declaratory plaintiff a reasonable apprehension that the

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* Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

patentee will bring suit if the activity in question continues." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997). Under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § § 355, 360cc, and 35 U.S.C. § 156, 271, 282), part one is satisfied in every instance where an ANDA is filed in accordance with 21 U.S.C. § 355(j), because 35 U.S.C. § 271(e)(2) provides that such a filing constitutes an act of infringement sufficient to trigger a justiciable case or controversy. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-78 (1990) (determining that the purpose for creating an act of infringement in 35 U.S.C. § 271(e)(2) was to "eliminat[e] the de facto extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly"); *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed .Cir. 1997).

We have never said that the traditional two-part test must be satisfied in every instance to find a justiciable case or controversy. Conversely, we have consistently held that "there is no specific, all-purpose test" for determining the existence of a case or controversy, either. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (describing the traditional two-part test as "often useful in evaluating complaints for declaratory judgments" but not mandatory in every instance). We have clarified that the "[s]atisfaction of this traditional two-part test is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate

enough to fulfill the 'actual controversy' requirement." *Fina Oil,* 123 F.3d at 1470.

Regardless of whether the two-part test is a constitutional necessity or not, the legislative history voices Congress' intent to apply the "reasonable apprehension" portion of the test in determining whether a court may determine the rights of an ANDA filer seeking relief. *See* H.R. Conf. Rep. No. 108- 391, at 836 (2003) ("Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction."). "As in all cases our task is to interpret the words of [the statute] in light of the purposes Congress sought to serve." *Chapman v. Houston Welfare Rights Org.,* 441 U.S. 600, 608 (1979).

II.

Because Teva filed an ANDA pursuant to 21 U.S.C. § 355(j) against Pfizer's '699 patent listed in the Orange Book, our application of the traditional test for an "actual controversy" turns solely on whether Pfizer has taken actions that give rise to a reasonable apprehension that it will sue Teva for infringement. The trial court dismissed Teva's declaratory judgment claim saying that no "actual controversy" existed under the Declaratory Judgment Act because, it concluded, Teva faced no "reasonable apprehension" that Pfizer would bring suit against it for infringing the '699 patent. *Teva Pharms. USA, Inc. v. Pfizer, Inc.,* No. 03-CV-10167, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

The 2003 amendments to the Hatch-Waxman Act provide for declaratory relief when an owner of a patent listed in the Orange Book fails to bring an infringement suit within 45 days after the ANDA is filed. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("Medicare Amendments") (codified in pertinent part at 21 U.S.C. § 355(j)(5)(C)(i)). These Medicare Amendments also give courts the authority to exercise jurisdiction over declaratory judgment actions brought by generic infringers "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5) (2003).

The Declaratory Judgment Act authorizes declaratory relief only in a "case of actual controversy." 28 U.S.C. § 2201 (2000). This requirement is the same as the "case or controversy" requirement of Article III of the Constitution. *See Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha,* 57 F.3d 1051, 1053 (Fed. Cir. 1995) ("The purpose of the declaratory action is to permit a threatened party to resolve its potential liability, but only when the relationship has progressed to an actual controversy, as required by Article III of the Constitution."). The Supreme Court has long held "that whatever else the 'case or controversy' requirement embodied, its essence is a requirement of 'injury in fact.'" *Schlesinger v. Reservists Comm. to Stop the War,* 418 U.S. 208, 218 (1974) (citation omitted).

The Supreme Court also has established criteria for evaluating whether a case passes the constitutional threshold of being a "case or controversy." In *Nashville, Chattanooga & St. Louis Railway Co. v. Wallace,* 288 U.S. 249, 259 (1933), the Court determined that it should "look not to the label which the Legislature has attached to the procedure

followed in the state courts, or to the description of the judgment which is brought here for review, in popular parlance, as 'declaratory,' but to the nature of the proceeding which the statute authorizes, and the effect of the judgment rendered upon the rights which the appellant asserts." Similarly, the Court in *Aetna Life Insurance Co. v. Haworth* decided that the federal Declaratory Judgment Act validly conferred jurisdiction on federal courts to issue declaratory judgments in appropriate cases. 300 U.S. 227 (1937). The Court "observed that the controversy would admit 'of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *Calderon v. Ashmus,* 523 U.S. 740, 746 (1998) (quoting *Aetna,* 300 U.S. at 241). Important to this case, the Court has "thus recognized the potential for declaratory judgment suits to fall outside the constitutional definition of a 'case' in Article III: a claim 'brought before the court(s) for determination by such regular proceedings as are established by law or custom for the protection or enforcement of rights, or the prevention, redress, or punishment of wrongs.'" *Id.* (quoting *Fairchild v. Hughes,* 258 U.S. 126, 129 (1922)). Such is the scheme created by the jurisdictional directives of Congress in the enactment of Hatch-Waxman and corresponding Medicare Amendments—the key issue being whether the courts are capable of achieving a final or conclusive determination that resolves the entire case or controversy.

Finding an actual controversy within the meaning of the Declaratory Judgment Act requires an analysis of the totality of the circumstances of each case. *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379 (Fed. Cir. 2004). The facts alleged must show a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. *Id.*

"Although the best evidence of a reasonable apprehension of suit comes in the form of an express threat of litigation, an express threat is not required." *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002) (citations omitted). Determining whether a reasonable apprehension of suit exists in a case controlled by the statutory and regulatory scheme of Hatch-Waxman requires a thorough analysis of the consequences and repercussions of each party's actions.

The most important basis for finding a reasonable apprehension of suit is Pfizer's listing of the '699 patent in the Orange Book. Pfizer's listing constituted an affirmative representation to the FDA and to competitors that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of any generic sertraline hydrochloride drug covered by the claims of the '699 patent. 21 U.S.C. § 355(b)(1) (2003). Although the listing in the Orange Book is a standard requirement for filing a NDA, it is a requirement that expresses a party's future intent to enforce its patent rights against those who subsequently file an ANDA and infringe. We have explained that the "reasonable apprehension" test serves to "protect[ ] quiescent patent owners against unwarranted litigation." *Arrowhead*, 846 F.2d at 736. Pfizer is not a defendant that "has done nothing but obtain a patent." *Id.* By listing its patent in accordance with 21 U.S.C. § § 355(b)(1) & (c)(2), Pfizer has informed the world that the '699 patent likely precludes anyone from marketing a generic sertraline hydrochloride product until it expires.

In evaluating whether there is a controversy, courts must take into account the injury that a generic drug manufacturer suffers when, as a result of actions taken by the brand-name manufacturer, it is delayed from marketing its product. Hatch-Waxman establishes that the first generic

applicant to file an ANDA containing a Paragraph IV certification is eligible, in some situations, for 180 days of marketing exclusivity, during which the FDA may not approve subsequent ANDAs for other generic versions of the drug. 21 U.S.C. § 355(j)(5)(B)(iv). Under the 1984 version of the Act, the 180-day period begins to run as of the earlier of: (i) the first day of commercial marketing by the first generic applicant; or (ii) a "decision of a court ... holding the patent which is the subject of the [Paragraph IV certification] to be invalid or not infringed." *Id.* § 355(j)(5)(B)(iv)(I-II). A court decision has been defined to include any district court decision obtained either by the first ANDA applicant or a subsequent ANDA applicant, through declaratory judgment or otherwise. *See 3M v. Barr Labs., Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002). If the first ANDA applicant triggers the 180-day period and promptly brings its product to market, then it is permitted, for 180 days, to be the only generic competitor for the name-brand drug. If, instead, a subsequent ANDA applicant triggers the 180-day period by obtaining a court decision, and the first ANDA applicant does not market its drug during that period, then the FDA may approve subsequent ANDAs, and the first ANDA applicant receives no exclusivity.

Although Congress' intention was for Hatch-Waxman to promote competition and speed generic entry into the market, the opposite has occurred as a result of strategies to "park" the 180-day period. Brand-name drug manufacturers may enter into an agreement with the first ANDA applicant whereby the first ANDA applicant agrees to refrain from entering the market for some period of time if the brand-name firm forgoes suing subsequent ANDA applicants during the statutory 45-day period. Such a course of conduct precludes the FDA from approving any subsequent ANDA applicants until: (i) 180 days after the first ANDA applicant

enters; (ii) the relevant patent expires; or (iii) a subsequent ANDA applicant can itself trigger the 180-day period. Essentially, the framework of Hatch-Waxman, combined with the conduct of the brand-name manufacturer, creates a cognizable injury to the subsequent generic ANDA filer. The delay created directly injures the subsequent ANDA applicant by depriving it of the opportunity to enter the market. The only way to eliminate this problem is for the subsequent ANDA applicant to bring a declaratory judgment action seeking a court decision of invalidity or noninfringement of the relevant patent.

Taking into account the specific regulatory context of the Hatch-Waxman regime, the "reasonable apprehension" test applied "to the extent consistent with the Constitution" is satisfied by Pfizer's conduct. *See* H.R. Conf. Rep. No. 108-391, at 836 (2003) ("[A] declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction" and the courts should "examine as part of their analysis the particular policies served by the Hatch-Waxman Act."). Cases arising under Hatch-Waxman do not present a classic patent declaratory judgment suit, and accordingly, the reasonable apprehension test should not be applied in the traditional manner. *See Fina Oil,* 123 F.3d at 1470 (discussing classic patent declaratory judgment suits). Typically, a potential competitor is legally free to market its product in the face of an adversely-held patent. In contrast, within the Hatch-Waxman regime, a subsequent ANDA applicant is not free to market-the applicant may suffer direct legal injury and require judicial relief based on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents and the likelihood of a future patent suit after the running of the 180-day period.

Against the backdrop of Hatch-Waxman, the totality of Pfizer's conduct must also be considered. *See* H.R. Conf. Rep. No. 108-391, at 836 (2003) ("In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where [an ANDA has been filed with a Paragraph IV certification and the patentee has not brought an infringement suit within 45 days]."). First, Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride. This shows both Pfizer's belief that its '699 patent is valid and its intent to assert the patent against infringers. "Related litigation may be evidence of a reasonable apprehension." *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992). Pfizer also has a history of asserting its patent rights against infringers of other patents. Considering that the '699 patent, which covers the brand name drug Zoloft ®, produced nearly 3 billion dollars in profit in 2002, economics and common sense dictate that Pfizer may well bring suit. Finally, Pfizer refused to grant Teva a covenant not to sue for infringement of the '699 patent.

Allowing Teva's declaratory judgment action is consistent with the "case or controversy" requirement of Article III of the Constitution because the suit will achieve a final determination that resolves the entire controversy between Teva and Pfizer. Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief. Consequently, under the Hatch-Waxman regime, Teva's injuries are traceable to Pfizer's conduct and those injuries could be redressed by a favorable decision. Therefore, Teva

maintains a reasonable apprehension of suit sufficient to confer jurisdiction under the Declaratory Judgment Act.

Appendix B — Opinion of the United States District Court for the District of Massachusetts Granting Defendant's Motion to Dismiss Filed December 8, 2003

United States District Court
District of Massachusetts

Civil Action No. 03-CV-10167-RGS

TEVA PHARMACEUTICALS USA, INC.

v.

PFIZER INC.

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION TO DISMISS

December 8, 2003

STEARNS, D.J.

On January 24, 2003, Teva Pharmaceuticals USA, Inc. (Teva), a manufacturer of generic pharmaceuticals, brought this declaratory judgment action against Pfizer Inc., seeking a determination that its generic version of sertraline hydrochloride would not infringe Pfizer's patented version of the drug, which is sold under the trade name Zoloft®. On March 10, 2003, Pfizer moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of

the absence of an actual controversy between the parties.[1] On November 6, 2003, the court heard oral argument on the motion to dismiss.

The Hatch-Waxman Act

This dispute arises under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (FFDCA), the complexities of which were explained by the Federal Circuit in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-1371 (Fed. Cir. 2002), as set out below.[2]

> Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, (the "Hatch Waxman Amendments" to the Federal Food, Drug and Cosmetic Act ("FFDCA")), Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. Under the Hatch Waxman Amendments, a manufacturer that seeks to

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1 After the initial briefing, the parties filed supplemental briefs to address a recent decision in a nearly identical case, Dr. Reddy's Laboratories, Ltd. v. Pfizer Inc., 2003 WL 21638254 (D.N.J., July 8, 2003).

2 The internal statutory citations to the FFDCA in *Andrx* were substantially modified by the recent revision of the Medicare law. The Medicare amendments, however, do not alter the substance of the ANDA process.

market a generic drug may submit an ANDA [Abbreviated New Drug Application] for approval by the FDA, rather than submitting a full New Drug Application ("NDA") concerning the safety and efficacy of the generic drug, and it may rely on safety and efficacy studies previously submitted by the pioneer manufacturer by submitting information showing the generic drug's bioequivalence with the previously approved drug product. *See* 21 U.S.C. § 355(j)(2)(A).

Also under the Hatch-Waxman Amendments, a pioneer drug manufacturer that holds an approved NDA is required to notify the FDA of all patents that "claim [ ] the drug for which the [NDA] applicant submitted the application...." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in its Approved Drug Products With Therapeutic Equivalence Evaluations (otherwise known as the "Orange Book"). Under 35 U.S.C. section 71(e)(1), it is not patent infringement to conduct otherwise infringing acts necessary to prepare an ANDA. Under section 271(e)(2), however, a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. As part of the approval process, an ANDA applicant must make a certification addressing each patent listed in the Orange Book that claims the drug. 21 U.S.C. § 355(j)(2)(A)(vii).... [T]he ANDA applicant must certify that (I) no such patent information has been submitted to the FDA;

> (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.
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> When an ANDA contains a paragraph IV certification, the ANDA applicant must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is not infringed, invalid, or unenforceable. 21 U.S.C. § 355(j)(2)(B)(i); 21 C.F.R. § 314.95(c)(6). The patentee then has forty-five days to sue the ANDA applicant for patent infringement, and the ANDA applicant may not file a declaratory judgment during this time (based on the filing of the ANDA application). 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does not sue, the ANDA will be approved. If the patentee does file suit, the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier.

The FFDCA provides an incentive to the first drug manufacturer who files an ANDA paragraph IV certification challenging a patent listed in the Orange Book. Under section 355(j)(5)(B)(iv), a 180-day period of marketing exclusivity is triggered by "the Secretary['s] receiv[ing] notice from the [first ANDA applicant] of [its] first commercial marketing of the drug" or by "a decision of a court in an action described

in [21 U.S.C. § 355(j)(5)(B)(iii)] holding the patent which is the subject of the certification to be invalid or not infringed." *Minnesota Mining and Mfg. Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002).

FACTS

Pfizer holds two patents on Zoloft®: U.S. Patent No. 5,248,699 (the '699 patent), and U.S. Patent No. 4,356,518 (the '518 patent). The '518 patent will expire on June 30, 2006.[3] The '699 patent expires on September 28, 2010. Pfizer has listed both patents in the Orange Book.

In July of 2002, Teva filed an ANDA, pursuant to 21 U.S.C. § 355(j), seeking the FDA's approval to market its generic version of sertraline hydrochloride. Teva also filed a paragraph III certification stating that it would not market the generic until Pfizer's '518 patent expired on June 30, 2006. Teva simultaneously filed a paragraph IV certification contending that its generic does not infringe the '699 patent or, alternatively, that the '699 patent is invalid.[4] On January 24, 2003, Teva filed this Complaint seeking a declaratory judgment of invalidity/non-infringement.

Teva was not the only manufacturer to file a sertraline hydrochloride ANDA. In 1999, Zenith Goldline Pharmaceuticals, Inc., now known as Ivax, filed the first sertraline hydrochloride ANDA. Like Teva, Ivax filed a paragraph III certification disclaiming any intention of

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[3] The '518 patent was to expire on December 30, 2005. The FDA, however, granted Pfizer a six month pediatric exclusivity extension.

[4] There is a third related Pfizer patent which is not implicated by Teva's filing.

selling the drug prior to the expiration of the '518 patent, as well as a paragraph IV certification challenging the '699 patent. As the first ANDA filer, were Ivax to prevail in the patent action, it would have been entitled under section 355(j)(5)(B)(iv) of the Act to a 180-day market exclusivity period. That period would begin to run either on the date of the first commercial sale of the generic drug, which given the paragraph III certification, would be June 30, 2006, or on the date of a court decision invalidating the '699 patent. In response to the ANDA, Pfizer brought an infringement action against Ivax within the forty-five day "stay-put" period mandated by section 355(j)(5)(B)(iii). Pfizer and Ivax then settled the case, with Ivax taking the rights to the exclusivity period. According to Teva, the settlement gives Pfizer a vested interest in protecting Ivax's exclusivity rights. This is so, because unless an intervening court decision opens the market further, Zoloft® will face only one generic drug competitor during the exclusivity period.

After Ivax filed its ANDA, Dr. Reddy's Laboratories (DLR) filed its own sertraline hydrochloride ANDA. Like Ivax and Teva, DLR challenged the '699 patent but not the '518 patent. Pfizer opted not to file suit against DRL within the "stay-put" period, causing DRL to bring an action for declaratory judgment in the district court in New Jersey. Pfizer then filed a motion to dismiss, similar in all respects to the motion pending before this court. On July 7, 2003, Judge Pisano allowed Pfizer's motion, holding that DRL had not demonstrated a reasonable apprehension of suit and that as a result no actual controversy existed between the parties. *Dr. Reddy's Laboratories, Ltd. v. Pfizer Inc.*, 2003 WL 21638254, at *6 (D.N.J., July 8, 2003).

DISCUSSION

"Under the Declaratory Judgment Act, 28 U.S.C. § 2201(a) (1994), a district court has jurisdiction over a declaratory judgment action only when there is an 'actual controversy.'" *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). "For an actual controversy to exist, '[t]here must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.'" *Id.* "Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). Hence, two question are before the court. Has Teva satisfied the two prongs of the "actual controversy" test and, if so, should the court exercise jurisdiction?

It is clear that Teva has satisfied the second prong of the test by filing the ANDA. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). ("[Section] 271(e)(2) provided patentees with a defined act of infringement [filing an ANDA] sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity."). *See also Andrx Pharmaceuticals, Inc.*, 276 F.3d at 1371 ("[U]nder section 271(e)(2), ... a generic drug manufacturer infringes a

patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent.").[5]

Whether Teva satisfies the first prong of the "actual controversy" test, requiring "an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit," is more problematic. "To put a putative infringer in reasonable apprehension of suit does not require an express charge of infringement and threat of suit; rather, such apprehension may be induced by subtler conduct if that conduct rises 'to a level sufficient to indicate an intent [on the part of the patentee] to enforce its patent,' *i.e.*, to initiate an infringement action." *EMC Corp.*, 89 F.3d at 811.

Teva, like DRL in *Dr. Reddy's Laboratories*, argues that Pfizer's actions (or inactions) to date have created a reasonable apprehension of suit. Teva cites the following indices of aggression: (1) Pfizer has listed the '699 patent in the Orange Book; (2) Pfizer has refused to grant Teva a covenant not to sue; (3) Pfizer has aggressively asserted its patent rights against alleged infringers of other of its patents; (4) Pfizer sued Ivax, the first generic manufacturer of

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[5] Section 271(e)(2) was intended to define a technical act of infringement for jurisdictional purposes to permit patent holders to bring suit against an ANDA filer within the forty-five day "stay-put" period. Conversely, the same jurisdictional act of infringement serves the ANDA filer when it seeks to file a declaratory judgment action after the forty-five day period expires. As Judge Pisano pointed out in *Dr. Reddy's Laboratories*, at *5, Pfizer's reliance on *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992), and *Bristol-Myers Squibb Co. v. Ivax Corp.*, 77 F. Supp. 2d 606, 619 (D.N.J. 2000), is misplaced as *Telectronics* is factually distinct, and *Bristol-Myers Squibb* did not address the import of section 271(e)(2).

sertraline hydrochloride; and (5) it is in Pfizer's self-interest "to leave a cloud of litigation" hanging over Teva as a means of protecting Ivax's 180-day exclusivity period.[6]

Like Judge Pisano in *Dr. Reddy's Laboratories*, I find that Teva has not satisfied the first prong of the "actual controversy" test. Teva argues that by listing a patent in the Orange Book, a patentee has declared its intention to sue any potential infringer. A blanket inference to this effect would cover every patent holder who listed a patent, thereby eliminating the second prong of the test. A patent holder may have reasons to sue for infringement, and all things depending, reasons not to sue.

Teva also points to Pfizer's refusal to enter a covenant not to sue. According to Teva, Pfizer has no reason not to sign the covenant (if it does not intend to sue) and by refusing to do so, has indicated its belief that it has substantive grounds on which to bring suit. Finally, Teva

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[6] Teva also argues that Pfizer returned without testing samples of the generic that Teva had mailed to Pfizer's counsel after the suit was filed. "Pfizer knows that testing would force its hand—either it would be required to tell Teva that it does not infringe its patent and provide it with a covenant not to sue, or to come clean with its intention to sue Teva for infringement." Teva Supplemental Memorandum, at 2. Whatever force this argument might have in the abstract—Pfizer maintains that it has no legal obligation to undertake an investigation of a competitor's product—it does not change the fact that it was Teva, and not Pfizer, who precipitated the product testing issue. Pfizer simply chose not to respond. This can hardly be considered conduct that exemplifies a "degree of adverseness" sufficient to trigger an actual controversy. *EMC Corp.*, 89 F.3d at 811-812. *Cf. Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992) (no apprehension of suit where patentee was approached by declaratory judgment plaintiff, and patentee did no more than defend the validity of its patent during negotiations).

maintains that Pfizer's foot-dragging in declaring its intentions one way or another is simply intended to forestall a court decision that might prematurely start the running of Ivax's market exclusivity period.[7] The bottom line is that there is nothing in the FFDCA that requires Pfizer to respond one way or another to Teva's request for a covenant not to sue. Nor is the fact that Pfizer may have an interest in seeing Ivax preserve its six-month quasi-monopoly relevant, given the intent of the Hatch-Waxman Amendments to encourage challenges to market-dominating pharmaceutical patents by so rewarding first filers. If anything, Pfizer's self-interest in protecting Ivax's exclusivity period makes the prospects of a lawsuit against Teva (or anyone else) even more remote.

Thus, all that remains is Teva's belief that it will be sued because Pfizer sued Ivax. This subjective belief does not amount to "an explicit threat or other action by the *patentee*" indicating the imminence of a lawsuit. *Amana Refrigeration*, 172 F.3d at 855 (emphasis added). It may well be, as Teva alleges, that Pfizer has outmaneuvered Teva by effectively partnering with Ivax. If so, Teva's frustration is understandable. But there is nothing in the FFDCA that makes Pfizer's conduct actionable.

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[7] Pfizer argues that this is a case of the pot calling the kettle black as Teva's obvious motive in filing this action is to rob Ivax of the benefits of its first filer status.

ORDER

For the foregoing reasons, Pfizer's motion to dismiss is *ALLOWED*. The dismissal will be entered without prejudice.

SO ORDERED.

/s/ Robert G. Stearns

United States District Judge

Appendix C — Opinion of the United States Court of Appeals for the Federal Circuit Denying Petition for Panel Rehearing and Rehearing En Banc Filed April 4, 2005

United States Court of Appeals for the Federal Circuit.

04-1186

TEVA PHARMACEUTICALS USA, INC.,
Plaintiff-Appellant,

v.

PFIZER, INC.,
Defendant-Appellee.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.

ORDER

A combined petition for panel rehearing and rehearing en banc was filed by the Appellant, and a response

thereto was invited by the court and filed by the Appellee.[1] The petition for rehearing was referred first to the merits panel that heard the appeal. Thereafter, the petition for rehearing en banc, response, and the amici curiae briefs were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

(2) The petition for rehearing en banc is denied.

(3) The mandate of the court will issue on April 11, 2005.

MAYER, GAJARSA, and DYK, Circuit Judges, would rehear the appeal en banc.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissents in a separate opinion.

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[1] Amicus curiae briefs were filed by:

1- The Federal Trade Commission.

2- The Generic Pharmaceutical Association.

3- Ivax Pharmaceuticals, Inc.

4- United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissents in a separate opinion.

FOR THE COURT

April 4, 2005
Date

s/ Jan Horbaly
Jan Horbaly
Clerk

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissenting from the order declining rehearing en banc.

The Court has denied the petition to review this case *en banc*. I must respectfully dissent from that denial. This is a critical issue under the Hatch-Waxman Act.[1] The failure of this court by *en banc* action to correct the *Teva* court's decision, 395 F.3d 1324 (Fed. Cir. 2005), allows the statutory procedures to be manipulated by the patent holders to the clear and foreseeable detriment of the generic drug industry.

The *Teva* court's reasonable apprehension analysis is the wrong test for a concrete, actual, or imminent injury in fact when considering the problem of a generic with a

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[1] The Patent Laws and Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271 and 282 (2000)), *as amended by* Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)).

second-filed ANDA certification.[2] Article III does not compel it, and the Supreme Court has rejected the doctrinal rigidity that *Teva* introduces. Our cases recognize reasonable apprehension, in the typical patent infringement case, as but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of law. The ANDA facts correspond to the typical infringement case in name only, and it is this court's constitutional duty to look at those facts in their proper context. The *Teva* court's misguided Article III analysis further thwarts Congress's clear intent to foster, through the detailed provisions of Hatch-Waxman, greater competition in generic pharmaceuticals.

I.

The question is whether Teva has shown a justiciable case or controversy within Article III. Congress unambiguously swept aside any additional limitation on jurisdiction potentially introduced by the Declaratory Judgment Act, 28 U.S.C. § 2201.

> [T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

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[2] The overall scheme of the Hatch-Waxman Act is described in detail in our decisions in *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) and *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002).

35 U.S.C.A. § 271(e)(5) (West Supp. 2004), as added by Pub. L. 108-173, 117 Stat. 2457 (Dec. 8, 2003). The law is clear that this justiciability issue has three elements: (1) a concrete, actual or imminent injury in fact; (2) fairly traceable causation between the injury and defendant's conduct; and (3) redressability. *See Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83, 103-04 (1998); *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.,* 454 U.S. 464, 472 (1982). Only the concrete injury in fact is disputed.

The cases treat the controversy requirements of Article III and § 2201 together and their approach is instructive here. Jurisdiction under § 2201 can be no broader than jurisdiction under Article III, yet the cases show that § 2201 is very broad indeed. Article III is no narrower. *See Aetna Life Ins. Co. of Hartford, Conn. v. Haworth,* 300 U.S. 227, 240 (1937) (§ 2201 "has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense[.]"). As the Supreme Court recognizes, the § 2201 controversy requirement is highly fact specific.

> The difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient

> immediacy and reality to warrant the issuance of a declaratory judgment.

Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941). The Supreme Court,[3] this court,[4] and our sister circuits[5] consistently apply this holding by looking to all the circumstances surrounding a controversy.

A.

The *Teva* majority opinion does not, and its reasons for failing to do so are not convincing. In far more difficult factual contexts the courts have nonetheless found "a concrete, actual or imminent injury in fact" satisfying Article III. In *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59 (1978), for example, the appellees challenged the constitutionality of the Price-Anderson Act. By that Act, Congress limited the aggregate tort liability of nuclear power plant operators for a single nuclear "incident." The appellant

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[3] *See Steel Co.*, 523 U.S. at 103-04; *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 81 (1978) (finding actual case and controversy where plaintiffs would sustain injury from operation of planned nuclear power plant, and injury was redressable by constitutionality challenge to Price-Anderson Act).

[4] *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996) (quoting *Md. Cas.*); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy).

[5] *See, e.g., Riva v. Mass.*, 61 F.3d 1003, 1009-10 (1st Cir. 1995); *Kidder, Peabody & Co., Inc. v. Maxus Energy Corp.*, 925 F.2d 556, 562-63 (2d Cir. 1991); *Oneida Tribe of Indians of Wis. v. State of Wis.*, 951 F.2d 757, 760 (7th Cir. 1991).

was a utility that was *constructing* nuclear power plants. The appellees, including persons "who live within close proximity of the *planned* facilities," challenged the statute under the Fifth Amendment. *Id.* at 67 (emphasis added). Their theory was that "*in the event of a nuclear accident* their property *would be* 'taken' *without any assurance* of just compensation." *Id.* at 69 (emphasis added). The court concluded that this theory stated a justiciable Article III controversy. *See id.* at 81 ("[A]ppellees will sustain immediate injury from the operation of the disputed power plants.").

The breadth of Article III standing in environmental cases sharply contrasts with the *Teva* court's narrow construction in this ANDA context. The Supreme Court has held that a concrete injury in fact, for Article III, is shown where a non-profit's members allege that a polluter's discharges, "and the affiant members' *reasonable concerns about the effects* of those discharges, directly affected those affiants' recreational, aesthetic, and economic interests." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 183-84 (2000) (emphasis added). The Court expressly ruled that conditional statements—that members would use a river for recreation if Laidlaw stopped discharging pollutants into it—sufficed to show concrete injury in fact under Article III. *Id.* at 184. Teva's injury in this case, by comparison, is far more immediate.

The facts showing Teva's "concrete, actual or imminent injury" are far easier to identify. Ivax filed the first ANDA on the active ingredient for Zoloft; Teva filed a subsequent or second ANDA. Teva certified that its proposed formulation would not infringe Pfizer's U.S. Patent No. 5,248,699, or that the patent was invalid. Pfizer had 45 days to sue Teva for this patent infringement, 35 U.S.C.

§ 271(e)(2)(A), and did not. Although Pfizer had sued Ivax, they settled out of court. Pfizer granted Ivax a royalty bearing license for the '699 patent, preserved Ivax's 180 day statutory exclusivity, and designed a comfortable duopoly set to begin on June 30, 2006 and potentially last 180 days past the '699 patent expiration in 2010. The FDA therefore could not approve Teva's generic drug until 180 days after Ivax's exclusivity expired—when either the '699 patent expired or was invalidated—and without FDA approval Teva could not market its product.

By settling with Ivax, Pfizer leveraged the Hatch-Waxman exclusivity to insulate the '699 patent from any validity challenge. Pfizer also insulated itself from any judicial determination of the metes and bounds of its '699 patent claim scope in relation to a design-around, a determination central to the proper function of our patent system. Because of this insular effect, Pfizer effectively extended—as against all but Ivax—the term of its underlying U.S. Patent No. 4,356,518, which expires on June 30, 2006, to coincide with the '699 patent's later expiration in 2010.[6]

This ties up Teva's investment in its proposed generic until at least 2010, precludes it from testing a potentially weak patent, precludes it from triggering the statutory

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[6] That is, the '518 patent claims the active ingredient in Zoloft. The '699 patent is an improvement. A generic, like Teva, that could design around the '699 but not the '518—or that thought it had found invalidating art for the '699 patent—would need a license to the '518 patent to enter the market, or face an infringement action. Once the '518 patent expired, Teva could confidently enter the market with a compound that did not infringe the '699 patent. But because of the Hatch-Waxman exclusivity, Pfizer insulated the '699 patent from any test in litigation. In practice this extends the '518 patent term until the '699 patent expires.

exclusivity period with a successful validity challenge, and precludes it from introducing an effective design-around, as is its right and as the patent law encourages. The live controversy is found on the face of this bottleneck under the statute.[7] Any of this defines a concrete, actual or imminent injury in fact within the meaning of Article III, and on that basis Teva states a justiciable controversy under § 2201.

B.

None of these problems can be found in the typical patent infringement context, in which this court has regularly tested immediate injury in fact by the reasonable apprehension test. Consistent with *Maryland Casualty*, this court has never held that Article III required that analysis. Quite to the contrary, this court has repeatedly observed that reasonable apprehension was simply a functional approach to typical patent infringement problems under § 2201. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996) (quoting *Md. Cas.*); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy). The purpose of the reasonable apprehension analysis "is to determine whether the need for judicial attention is real and immediate." *BP Chems.*, 4 F.3d at 978. The *Teva* court

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[7] *Cf. Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 n. 18 (D.C. Cir. 1998) ("It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.").

ignores this precedent and reads general infringement policy considerations into Article III, where they do not belong.

The contextual differences between the second ANDA filer and the typical patent infringement case make the reasonable apprehension test inappropriate for this action. By guiding the patentee's conduct in the typical case, the reasonable apprehension analysis allows the patentee to avoid litigation. Identifying a justiciable controversy in terms ~~of a threat~~ of infringement litigation, the doctrine establishes the circumstances in which the uncertainty of legal rights materially harm a potential infringer in the marketplace. The injury facing Teva in this case is different in kind, but no less actionable.

Teva's injury does not depend on threats from the incumbent. In view of the statute, the injury exists independent of any threat, and the policy motivation for applying the reasonable apprehension test is completely lacking. There is no sense in the court demanding the incumbent to brandish the threat of infringement actions, even beyond the act of listing a patent in the Orange Book, given a statutory system that encourages the incumbent to do everything possible to prevent its patents from being put in play. No incumbent will ever make the threat, if it can simply ride out the term in the listed patent.[8] From first principles, a fact specific analysis shows that the reasonable apprehension test is not designed for this case.

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[8] *See Minn. Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002).

II.

The language of § 271(e)(5) grants Article III jurisdiction to the maximum extent possible. The statute provides that the courts shall *have* subject matter jurisdiction. The majority's analysis in *Teva* of the legislative history to the 2003 Act[9] seems addressed to this point, but its reasoning is unconvincing.

The statute specifically provides that the courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action." The court, therefore, has a Congressional directive to refrain from applying any jurisdictional limitation crafted by the courts or found in § 2201. The *Teva* court overlooks this basic point.

The *Teva* court further focuses on the language originally introduced for § 271(e)(5), which provided that an incumbent's failure to sue within 45 days "shall establish an actual controversy between the applicant and the patent owner." *Teva,* 395 F.3d at 1336. In conference the language was changed to a provision that the courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over these actions. *Id.* The court concludes that § 271(e)(5) was "not meant to automatically bestow district court jurisdiction over actions such as Teva's." *Id.* This conclusion is contrary to the plain language of § 271(e)(5). The change in language bestowed full Article III jurisdiction and simply recognizes the court's role in declaring when the

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[9] Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)) [hereinafter "2003 Act"].

judicial powers under Article III extend to this action. It does not bear on the proper scope of Article III.

The *Teva* court also focuses on a Committee Report accompanying the modified 2003 Act. The language in the Report cannot contradict the plain language of § 271(e)(5). A legislative enactment cannot limit the judicial power under Article III, and, *a fortiori,* language in a Committee Report that misstates our Article III jurisprudence cannot bind this court.

Ultimately, the idea that § 271(e)(5) suggests a limitation on standing is misplaced, given the plain language of Hatch-Waxman. The statute provides an express mechanism for generics to challenge, with declaratory actions, the claim scope or validity of listed patents. Under this statutory scheme, it is court challenges by generic drug companies that limit incumbent overreaching by submitting over-inclusive lists of patents applicable to any given branded formulation. Congress's intent to foster early generic market entry precludes any real argument for any limitation. Certainly under the circumstances of this case, Teva's declaratory action is the ideal method to police Pfizer's strategic manipulation of the Hatch-Waxman exclusivity provisions. Delayed resolution of the bottleneck facing Teva serves no purpose, as by then the patents at issue will have expired. There is no basis for precluding this suit on Article III grounds.

III.

The *Teva* court's Article III analysis distorts longstanding Supreme Court jurisprudence and misapplies the decisions of this court. Teva has presented a justiciable controversy, and the courts should decide it. Worst of all, the

Teva court's Article III analysis forestalls legislative correction. The court should have corrected this error *en banc*. I respectfully dissent from the refusal to do so.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissenting from the order denying rehearing en banc.

This case presents an important question under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc (2000) and 35 U.S.C. §§ 156, 271, 282 (2000))—whether a patent holder can delay Food and Drug Administration ("FDA") approval of an application for a competing generic drug by the simple expedient of refusing to sue for infringement. Here there is a present controversy over Teva's right to secure approval of its Abbreviated New Drug Application ("ANDA"), plainly adequate to satisfy the requirements of Article III.

The Declaratory Judgment Act, 28 U.S.C. § 2201 (2000), and the 2003 Medicare Amendments, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, Pub. L. No. 108-173, 117 Stat. 2066, 2448-69 (codified in pertinent part at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)), were designed to create a declaratory judgment remedy in circumstances permitted by Article III. The panel's holding, relying on earlier decisions of our court, that Article III bars such a remedy unless "a reasonable apprehension of *imminent* suit" exists is incorrect. *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005). I dissent from the denial of rehearing *en banc*.

I.

The plain language of the 2003 Medicare Amendments requires that in the Hatch-Waxman context the federal courts allow declaratory judgment actions to the full extent allowed by Article III. 35 U.S.C.A. § 271(e)(5) ("[C]ourts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed."). Even if the legislative history could be read as approving our reasonable apprehension test, that history cannot overcome the plain language of the statute. So we must decide whether Article III is satisfied.

There are relatively few Supreme Court cases dealing with Article III and declaratory judgments, but the few cases that do exist provide no support for a reasonable apprehension of imminent suit requirement. The declaratory judgment statute was designed to deal with a situation in which the declaratory judgment defendant declined to bring suit, i.e., in which there was no reasonable apprehension of imminent suit. The Supreme Court case upholding the statute involved just such a situation—one in which there was no imminent risk of suit because the potential plaintiff declined to sue. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937). In that case, the insured on several policies stopped making premium payments and made repeated claims for benefits on account of total and permanent disability. *Id.* at 237-38. Aetna refused to pay benefits because it contended that the insured was not disabled and that the policies had lapsed due to nonpayment. *Id.* at 238. The insured failed to bring suit, so Aetna filed for a declaratory judgment that the insured was not disabled and that the policies had lapsed. *Id.* at 239. The Court found that

these facts gave rise to a controversy within the meaning of Article III, stating "[t]here is here a dispute between parties who face each other in an adversary proceeding.... The dispute is defined and concrete, not hypothetical or abstract.... It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts." *Id.* at 242.

Likewise, the Ninth Circuit, in a case in which the plaintiff faced a risk of liability rather than suit, has held that "[a]n action for a declaratory judgment ... is a case or controversy if the plaintiff has a real and reasonable apprehension that he will be subject to *liability,*" not suit. *Societe de Conditionnement en Aluminium v. Hunter Eng'g Co., Inc.,* 655 F.2d 938, 944 (9th Cir. 1981) (emphasis added).[1] The First Circuit has even more directly addressed the issue in *Sallen v. Corinthians Licenciamentos LTDA,* 273 F.3d 14 (1st Cir. 2001), and adopted a view that conflicts with the panel decision in this case. There, a World Intellectual Property Organization ("WIPO") panel found Sallen to be a cybersquatter and ordered his domain name transferred to Corinthians Licenciamentos LTDA ("CL"). *Id.* at 21-22. Sallen filed suit in federal district court seeking a declaration that under United States law (which allowed a challenge to the WIPO decision) he was entitled to the domain name. *Id.* at 22. The district court dismissed the

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[1] That case involved a manufacturer that filed for declaratory judgment of invalidity of the defendant's patent after a potentially unauthorized person working for the defendant threatened a third party with suit if the third party purchased the plaintiff's equipment. *Id.* at 941, 944-45. The third party purchased the equipment. *Id.* at 941. A hold harmless provision in the contract between the third party and the plaintiff placed the plaintiff in reasonable apprehension of liability. *Id.* at 945.

case because CL had no intent to sue Sallen under United States law. *Id.* On appeal, the First Circuit rejected CL's argument that a reasonable apprehension of suit is required to satisfy Article III:

> CL claims that a reasonable apprehension of suit is required to meet Article III's case or controversy requirement. *But this is not the only way to establish the existence of a case for purposes of Article III. The reasonable apprehension of suit doctrine exists to cabin declaratory judgment actions where the only controversy surrounds a potential, future lawsuit.* That is not this case.

Id. at 25 (internal citations omitted and emphasis added). The court found that United States law "provides a registrant who has lost a domain name ... with a cause of action for an injunction returning the domain name if the registrant can show that she is in compliance with" United States law. *Id.* at 26. Thus, the court found that the controversy in issue was certain and that "a certain controversy renders the 'reasonable apprehension' question irrelevant." *Id.*

In my view, the First Circuit is correct: the proper test under Article III is whether there is a present concrete controversy, and the panel here applied an incorrect test. The panel here also reached the wrong result in this case by relying on that erroneous test.

II.

Here it seems to me that there are three potential controversies:

1. There is a potential controversy over whether the ANDA filing itself was an infringement. I doubt whether this, standing alone, satisfies Article III because Pfizer seems not to care whether such an infringement occurred. *Textron Lycoming Reciprocating Engine Div., AVCO Corp. v. UAW,* 523 U.S. 653, 661 (1998) (finding no constitutional controversy where the declaratory judgment defendant had no "interest in defending the binding nature of the contract").

2. There is also a potential controversy over whether Teva should be allowed to manufacture and market the drug without incurring damages for infringement. The problem here is that Teva has not alleged that it intends to market or sell the drug at any time in the near future or that it is being prevented from doing so by the risk of infringement damages. Instead, Teva alleges only that the filing of its ANDA constituted technical infringement; that Pfizer did not file suit within the 45-day period; that Pfizer included the '699 patent in the Orange Book; and that Pfizer tends to enforce its patents through litigation. (J.A. at 52.) Unless Teva actually is about to manufacture or sell the drug, there would seem to be no case or controversy under this theory. *Societe de Conditionnement,* 655 F.2d at 944.

3. The third potential controversy is over whether Teva's ANDA should be approved earlier than 180 days after Ivax commences marketing. In my view, there is a present and concrete controversy over Teva's right to such an approval, which satisfies the requirements of Article III. The Hatch-Waxman Amendments provide for the right to secure resolution of the controversy through a declaratory judgment.

Ivax earlier filed a paragraph IV certification regarding the '699 patent and then settled with Pfizer. Thus, Ivax will enjoy a 180-day exclusivity period beginning with

the *earlier* of (1) the first day it markets its generic drug (which cannot be earlier than June 30, 2006) or (2) the date that the '699 patent is held invalid or not infringed in the decision of a court.[2] Because of the paragraph IV certification, Teva's application cannot be approved by the FDA until after Ivax's 180-day exclusivity period ends. *Teva*, 395 F.3d at 1328, 1330. In other words, the running of the exclusivity period could be triggered before Ivax's first marketing date if Teva could secure a declaratory judgment of non-infringement or invalidity. Approval of Teva's ANDA would follow 180 days thereafter.

Normally, one would expect that the approval issue would be litigated between Teva and the FDA, but, as we recognized in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002), Congress provided that approval would depend on the outcome of litigation between private parties (the patent owner and the potential infringer) over the questions of infringement and validity.[3] There is certainly a concrete controversy between Pfizer (and Ivax) and Teva over when Teva's ANDA should be approved. Both Pfizer and Ivax want the approval of Teva's application delayed. Teva wants to avoid delay. The question of delay turns on infringement

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[2] To be sure, Pfizer's failure to bring suit within the 45-day period specified in section 21 U.S.C. § 355(j)(5)(B)(iii) means that the approval of the ANDA will not be delayed under that section, but despite Pfizer's failure to sue, 21 U.S.C. § 355(j)(5)(B)(iv) will bar approval until 180 days after Ivax markets the drug unless there is an earlier holding of non-infringement or invalidity.

[3] *See also Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

and validity.[4] Under these circumstances, I think there is a case or controversy within the meaning of Article III, and that the questions of infringement and validity should be addressed. The panel appears to recognize the existence of a controversy, but holds that the controversy is insufficient for purposes of Article III.[5]

I respectfully disagree. Under the panel's decision Teva lacks any remedy to contest the delay in its ANDA approval. I agree with Judge Mayer and Judge Gajarsa that Article III does not require such unfairness.

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[4] While the '518 patent imposes an additional limitation on the approval of Teva's ANDA such that it could not be approved until the '518 patent expires (June 30, 2006), it is hardly premature to litigate the approval date since litigation over infringement and invalidity of the '699 patent could itself consume a significant time.

[5] The panel states that "[t]he fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer." *Teva*, 395 F.3d at 1338.

Appendix D — 21 U.S.C. § 355(j)(5)(C)

TITLE 21. FOOD AND DRUGS

CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

* * *

§ 355. New drugs

* * *

(j) Abbreviated new drug applications

* * *

(5) * * *

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

Appendix E — 149 Cong. Rec. S15884-86 (Nov. 25, 2003)

Congressional Record — Senate
Proceedings and Debates of the 108th Congress,
First Session
Tuesday, November 25, 2003

[Page S15882]

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003—CONFERENCE REPORT

[Page S15584]

TITLE XI

Mr. KENNEDY. Mr. President, I oppose the Medicare bill before the Senate, but I want to express my understanding of the refinements of the Hatch-Waxman Act found in Title XI of the Medicare bill now before the Senate. I was deeply involved in the negotiations of these provisions in the conference. The Hatch-Waxman Act, which passed in 1984, reflects efforts by the Congress to promote two policy objectives: to encourage brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, and to enable competitors to bring cheaper, generic copies of those drugs to market as quickly as possible.

The Hatch-Waxman Act has worked very well for almost 20 years. It has provided the incentives necessary to bring the many medicines to market that have so transformed the shape of modern medical practice. And it has brought

generic drugs to market faster than ever, saving consumers billions of dollars.

As the Federal Trade Commission has shown, however, in recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the Hatch-Waxman Act found in Title XI represent refinements to the present system that will stop these abuses, will restore the original balance the law intended, and will ensure Americans more timely access to affordable pharmaceuticals. Most significantly, the Hatch-Waxman provisions in this bill limit brand-name drug companies to only one 30-month stay of approval of generic drugs. This change will stop the multiple, successive 30-month stays that the Federal Trade Commission identified as having delayed approval of generic versions of several blockbuster drugs and cost consumers billions of dollars. It also restructures how the 180-day generic exclusivity provisions work. The 180-day exclusivity gives a generic company 180 days during which it is the only generic competitor to the brand drug. The exclusivity is a very valuable incentive for generic companies. The exclusivity encourages generic companies to challenge patents that are likely invalid or not infringed and, because it goes to the first generic applicant to challenge a brand-name drug patent, it encourages challenges of those patents as soon as possible. These incentives mean that consumers will be able to enjoy the lower prices provided by generic companies sooner rather than later.

The Federal Trade Commission reports that the exclusivity has at times been parked through collusive agreements between brand and generic companies. Parking the exclusivity has blocked other generic companies from getting to market and has cost consumers billions of dollars.

The Hatch-Waxman provisions in this bill are intended to prevent parking of the exclusivity. It does this by providing for several situations in which a generic company with the exclusivity forfeits the exclusivity, clearing the way for other generic companies to bring their products to market.

The Hatch-Waxman provisions in this bill also make the exclusivity available only with respect to the patent or patents challenged on the first day generic applicants challenge brand drug patents, which makes the exclusivity a product-by-product exclusivity rather than a patent-by-patent exclusivity, and the exclusivity is available to more than one generic applicant, if they all challenge patents on the same day.

Mr. SCHUMER. Mr. President, will the Senator yield for a question?

Mr. KENNEDY. Yes, I will yield to my friend from New York.

Mr. SCHUMER. Thank you, Mr. President. Let my just say, before I ask my question, that I want to thank the Senator from Massachusetts, and the senior Senator from New Hampshire, for their leadership on this issue. The

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Senator from Massachusetts, as chair of the HELP Committee last year, took up the generic drug bill authored by the senior Senator from Arizona and myself, saw it through the HELP Committee, and managed its passage by the full Senate. This year, the senior Senator from New Hampshire approached me to work together to come up with the generic drug bill that served as the basis for what is in

this bill, and he brought it through the HELP Committee, offered it as an amendment to the prescription drug bill in the Senate, where it was accepted 94-1, and defended it very ably in conference with the House. So, again, I would like to thank both distinguished chair and ranking member of the HELP Committee for their leadership on this issue.

Of course, I also want to thank the senior Senator from Arizona, without whose leadership over the past several years we would not be where we are today on such an important consumer issue.

As for my question, I understand that a generic applicant that has the 180- day exclusivity will forfeit the exclusivity if it has failed to market its product 75 days after certain events have happened with respect to itself or another generic applicant and with respect to each of the patents that gives the generic applicant its generic exclusivity. Is that correct?

Mr. KENNEDY. That is correct.

Mr. SCHUMER. And am I correct that one of these events is when "a court enters a final decision" that the patent is invalid or not infringed by the drug of the generic applicant?

Mr. KENNEDY. The Senator is correct.

Mr. SCHUMER. And am I correct that a final court decision under this provision includes the kind of court decision recognized in the Teva v. Shalala opinion?

Mr. KENNEDY. Yes, I very much appreciate your question on this point. We do intend that a court decision like

the one in the D.C. Circuit's 1999 decision in Teva v. Shalala-a decision dismissing a declaratory judgment action for lack of subject matter jurisdiction because the patent owner has represented that the patent is not infringed-will count as a court decision under the new "failure to market" provision. Under the failure to market provision, the conditions for forfeiture are intended to be satisfied when a generic company has resolved patent disputes on all the patents that earned the first-to-file its exclusivity. After a court decision such as that at issue in Teva v. Shalala, the patent owner is estopped from suing the generic applicant in the future and the patent dispute is resolved. So these sorts of decisions should be recognized as court decisions under the failure to market provision.

I'd also like to point out the importance of the declaratory judgment provisions that are in the Senate bill and are retained in modified form by the conferees in the conference report now before the Senate. Amendments made by this bill to both the Federal Food, Drug, and Cosmetic Act and Title 35 clarify that generic applicants may bring declaratory judgment acts to ensure timely resolution of patent disputes. These provisions authorize a generic applicant to bring a declaratory judgment action to obtain a judicial determination that a listed patent is invalid or is not infringed if the applicant is not sued within 45 days of having given notice to the patent owner and brand-name drug company that it is challenging the patent. This clarification of a generic applicants right to bring a declaratory judgment action is crucial to ensuring prompt resolution of patent issues, which is essential to achieve our goal of speeding generic drugs to market.

It's worth pointing out that the Hatch-Waxman Act has always provided that patent owners and brand drug

companies can bring patent infringement suits against a generic applicant immediately upon receiving notice that the generic applicant is challenging a patent. The declaratory judgment provisions in Title XI of this bill simply level the playing field by making it clear that the generic applicant can also seek a prompt resolution of these patent issues by bringing a declaratory judgment action if neither the patent owner nor the brand drug company brings such a suit within 45 days after receiving notice of the patent challenge.

Mr. McCAIN. Mr. President, will the Senator yield for a question?

Mr. KENNEDY. Yes, I will yield.

Mr. McCAIN. Will the Senator please explain for me and our colleagues the purpose of the provision in Title XI that amends Title 35 to say that courts must hear declaratory judgment actions brought by generic applicants?

Mr. KENNEDY. Certainly. The provision in Title 35 is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution. We fully expect that, in almost all situations where a generic applicant has challenged a patent and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe. The mere fact that neither

the patent owner nor the brand drug company has brought a patent infringement suit within 45 days against a generic applicant does not mean there is no "case or controversy." The sole purpose of requiring the passage of 45 days is to provide the patent owner and brand-name drug company the first opportunity to begin patent litigation. Inaction within the 45-day period proves nothing, as there are tactical reasons why a patent owner or brand drug company might refrain from bringing suit on a patent within 45 days.

For example, the brand drug company might have several patents listed in the Food and Drug Administration's Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve. The suit on one patent would automatically stay approval of the generic application until the lawsuit is resolved or the 30 months elapses. Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement suit.

Or for patents on which no 30-month stay is available, the brand drug company could sit back to create uncertainty and similarly delay generic entry by delaying resolution of those patents. Or when generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.

In each of these and in other circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45- day period. We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

Mr. McCAIN. Mr. President, will the distinguished Senator yield?

Mr. KENNEDY. Yes, I will yield.

Mr. McCAIN. Mr. President, I'd like to ask the Senator if it is the intent of this legislation that the declaratory judgment provisions in this bill, in particular, the change to Title 35, will be available immediately to help generic drug applicants who are now in federal court seeking declaratory judgments that listed drug patents are invalid or are not infringed by their product?

Mr. KENNEDY. I agree with the distinguished Senator from Arizona. It is clearly our intent that, under these

[Page S15886]

provisions, courts considering jurisdictional challenges to declaratory judgment actions brought by generic drug companies should apply the standards set forth in this bill to such challenges in any case pending (either in the trial court or on appeal) at the time of enactment in order to resolve

patent issues as soon as possible and to clear the way for quicker generic entry.

Mr. McCAIN. I thank the Senator for his answer and for his leadership on these issues. His experience and technical expertise have been invaluable. I would also like to thank my friend, the senior Senator from New York, who has worked with me these many years on this legislation. His dedication to American consumers and his commitment to restoring fairness to the drug industry must be commended. The senior Senator from New Hampshire must also be recognized for leadership on this issue in his committee, in the Senate, and in the conference on this bill. I would also like to thank the staffs of all three of these Senators, who have worked tirelessly on behalf of this issue. I ask unanimous consent that a letter from Chairman Muris of the Federal Trade Commission about the value of the declaratory judgment provision in Title 35 be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

FEDERAL TRADE COMMISSION,
Washington, DC, October 21, 2003.

Hon. JUDD GREGG,
Hon. EDWARD M. KENNEDY,
Senate Committee on Health, Education, Labor, and Pensions, Washington, DC.

DEAR CHAIRMAN GREGG AND RANKING MEMBER KENNEDY: In written testimony submitted to the Senate Judiciary Committee on August 1, 2003, for a hearing entitled, "Examining the Senate and House Versions of the 'Greater Access to Affordable Pharmaceuticals Act,'" the

Federal Trade Commission commented on both the Senate and House-passed bills that reform the Hatch-Waxman generic drug approval process. The reforms are nearly identical to recommendations contained in the FTC's July 2002 study entitled, "Generic Drug Entry Prior to Patent Expiration."

I understand that one particular provision contained in the Senate-passed version is of particular interest now on the bills proceed through the conference process. Specifically, the Senate bill adds a provision clarifying that if a brand-name company fails to bring an infringement action within 45 days of receiving notice of an abbreviated new drug application (ANDA) containing a paragraph IV certification, the generic applicant can bring a declaratory judgment action that the patent is invalid or not infringed. Without commenting on the provision's constitutionality, the Commission has stated that "the Senate provision may help ensure that a federal court has subject matter jurisdiction to resolve the patent issues." While I defer to others as to the constitutionality of the Senate provision, I note that a court's dismissal of a declaratory judgment action for lack of controversy may resolve uncertainty concerning whether a generic product infringes a brand-name company's patent. It also can reduce the incentives for the brand-name company and the first generic applicant to park the 180-day exclusivity. Without the right to seek a declaratory judgment, a subsequent generic applicant that develops a clearly non-infringing product cannot trigger the first generic applicant's exclusivity because the subsequent generic applicant will not be sued for patent infringement by the brand-name company. If the brand-name company and the first generic applicant agree that the generic will not begin commercial marketing, then the 180-day exclusivity becomes an absolute bar to any general entrant. Moreover, speedier resolution of patent

infringement suits will redound to the benefit of consumers by resolving any possible uncertainty that prevents a generic applicant from marketing its products. If also will allow for the simultaneous running of the periods for FDA approval and for the resolutions of patent infringement issues.

For these reasons, I believes the declaratory judgment provision in the Senate-passed bill would be a useful mechanism to reduce uncertainty in the Hatch-Waxman process and potentially could speed access of generic drugs to consumers.

Sincerely,
TIMOTHY J. MURIS.

Appendix F — H.R. Conf. Rep. No. 108-391, at 836 (2003)

HOUSE OF REPRESENTATIVES
108TH CONGRESS
1st Session

Report 108-391

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

CONFERENCE REPORT
to accompany
H.R. 1

NOVEMBER 21 (legislative day, NOVEMBER 20), 2003—
Ordered to be printed

[Page 832]

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

[Page 835]

Provisions Related to Hatch-Waxman Law

[Page 836]

DECLARATORY JUDGMENTS

The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers

and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. See, e.g., *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002). In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

SEP 7 - 2005

(2)

No. 05- 48

IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

PFIZER, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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September 7, 2005

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

QUESTION PRESENTED

Whether the court below properly determined, on the particular factual record of this declaratory-judgment action, that there was not a ripe Article III case or controversy for it to adjudicate, particularly given that the declaratory-judgment plaintiff did not intend to market the potentially infringing product in question for years, if ever, and given that the plaintiff acknowledged that the declaratory-judgment defendant had no current interest in asserting its patent rights against the plaintiff.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondent Pfizer Inc. ("Pfizer"), designated "Pfizer, Inc." in the caption, states that it has no parent and no publicly held company owns 10% or more of its stock.

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RESPONDENT'S BRIEF IN OPPOSITION

STATEMENT OF THE CASE

In this action, Petitioner Teva Pharmaceuticals USA, Inc. ("Teva") seeks an advisory opinion on whether a generic pharmaceutical that it may someday attempt to market, but for which it concededly will not seek FDA approval until at least July 2006, infringes a patent that Teva itself alleges respondent Pfizer has no present interest in asserting against Teva. Affirming the district court, the Federal Circuit properly declined the invitation to embark on such a hypothetical, speculative inquiry in light of the Article III requirement of an actual and concrete "Case[]" or "Controvers[y]." Such a routine justiciability determination, based on the specific factual circumstances of this case, and involving a statutory scheme that has since been amended to alter the analysis fundamentally in future cases, does not warrant this Court's review.

A. The Statutory Scheme Governing Expedited FDA Approval of Generic Pharmaceuticals.

1. Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, manufacturers of both innovative and generic pharmaceuticals must follow procedures for Food and Drug Administration ("FDA") approval of a drug, which include the filing of a New Drug Application ("NDA"). *Id.* § 355(a). In the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282), (commonly referred to as the Hatch-Waxman statute), however, Congress alternatively provided for special, expedited procedures for the introduction of generic pharmaceuticals into the marketplace. Reflecting a balance between the policies of creating incentives for innovating new pharmaceuticals and

allowing the prompt introduction of less-expensive generic products into the marketplace, the expedited Hatch-Waxman procedures allow manufacturers of generic pharmaceuticals that are identical and bioequivalent to drugs previously approved by the FDA to obtain approval by filing an Abbreviated New Drug Application ("ANDA"), rather than a full NDA. 21 U.S.C. § 355(j).

The process for approval of such a tag-along ANDA application builds off of the filing of the earlier, completed NDA for a new pharmaceutical product. In conjunction with its NDA filing, the NDA applicant must supply to the FDA a list of all patents "claim[ing] the drug for which the applicant submitted the application" and "with respect to which a claim of patent infringement could reasonably be asserted." *Id.* § 355(b)(1); *see also id.* § 355(c)(2). The FDA publishes these patent listings in an appendix to the "Orange Book," *Approved Drug Products With Therapeutic Equivalence Evaluations*, *available at* http://www.fda.gov/-cder/ob/default.htm (last visited Sept. 1, 2005).

An ANDA filer for FDA approval may, upon demonstrating the identity and bioequivalence of its product with the prior NDA product, rely upon the earlier drug's safety and efficacy studies. 21 U.S.C. § 355(j)(2)(A); Pet. App. 4a. Accompanying such an ANDA filing, a generic applicant must make one of four possible certifications with respect to every patent listed in the Orange Book under the NDA on which the ANDA is premised. A "paragraph I" certification states that required patent information was not filed by the NDA holder with the FDA. A "paragraph II" certification indicates that the patent in question has expired. A "paragraph III" certification states that the patent will expire on a particular date in the future, in which case the FDA cannot approve the ANDA until after that expiration date has passed. And a "paragraph IV" certification states that "the patent is invalid or will not be infringed by . . . the new drug." *Id.* § 355(j)(2)(A)(vii)(I-IV).

Under the Hatch-Waxman Act, while steps necessary to prepare an ANDA do not constitute infringement of an Orange Book patent (even if those acts might otherwise be infringing), the actual filing of an ANDA containing a paragraph IV certification is deemed a statutory act of patent infringement. 35 U.S.C. § 271(e)(2). Moreover, an applicant's filing of an ANDA incorporating a paragraph IV certification starts a 45-day period during which the patentee may sue the ANDA applicant for this statutory infringement, and during which the ANDA applicant may not bring a declaratory-judgment action with regard to the patent that was the subject of the certification. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee sues for infringement during this period, the FDA may not approve the ANDA for thirty months, unless the lawsuit is resolved in favor of the ANDA applicant. *Id.* If the 45-day period expires without the patentee bringing suit, the FDA may approve the ANDA. *Id.*

Under the statute, the first ANDA applicant to file a paragraph IV certification receives the benefit of a 180-day exclusivity period during which the FDA may not approve any other paragraph IV ANDAs based upon the same NDA. *Id.* § 355(j)(5)(B)(iv). Under the statutory regime applicable to this case (but that has since been amended, as discussed below), the 180-day exclusivity period began to run upon the earlier of two events: The date when the ANDA product is first commercially marketed, or "the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed." *Id.* § 355(j)(5)(B)(iv).

2. In 2003, however, Congress amended this statutory scheme in Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "Medicare Amendments"). The Medicare Amendments make several pertinent changes to the ANDA approval process.

Most significantly, the Medicare Amendments revise the provisions governing the 180-day exclusivity period for a first ANDA filer in all ANDAs filed after December 8, 2003. The new provisions change the statute so that, rather than have a court-decision alternative as a possible means to begin the 180-day exclusivity period, the 180-day exclusivity period begins to run only on the date of first commercial marketing, 21 U.S.C. § 355(j)(5)(B)(iv), subject to a forfeiture of the exclusivity under six circumstances: (1) if the first applicant fails timely to market the pharmaceutical; (2) if the first applicant withdraws its ANDA; (3) if the first applicant withdraws its paragraph IV certification; (4) if the first applicant fails to obtain tentative approval within specified time periods; (5) if the first applicant enters into an agreement found by the Federal Trade Commission ("FTC") or a court to violate the antitrust laws; or (6) if all patents subject to paragraph IV certifications expire. *Id.* § 505(j)(5)(D). Thus, while a court judgment of invalidity or non-infringement can factor into the exclusivity analysis, it does so only in an entirely different way from the pre-2003 regime at issue in this case — specifically, only as a subsidiary component of the "failure to market" forfeiture analysis. *Id.* § 355(j)(5)(D)(i)(I)(aa). These new criteria for starting the 180 days and the forfeiture provisions (with the exception of the collusive agreement forfeiture provision, which is not at issue here) apply only prospectively to ANDAs filed after December 8, 2003, and thus do not apply to this case. Pet. App. 6a-7a & n.3.

The Medicare Amendments also impose a new requirement upon ANDA applicants who file declaratory-judgment actions regarding Orange Book patents after the expiration of the 45-day period. Specifically, they require that such ANDA applicants offer confidential access to the ANDA materials to allow the patentee or NDA holder to evaluate issues pertaining to infringement. 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). The Medicare Amendments also state that, after the 45-day period, "courts of the United

States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought . . . under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

B. The FDA's Approval of Zoloft®, The Subsequent ANDAs, And The Litigation Below

1. Pfizer manufactures and sells Zoloft®, a pharmaceutical for treating certain mood and anxiety disorders. The active ingredient in Zoloft® is sertraline hydrochloride, which acts by inhibiting the uptake of serotonin in the brain. In obtaining its NDA for this compound, Pfizer filed with the FDA a listing of patents covering Zoloft® or a method of use for Zoloft®, and the FDA published these patents in the Orange Book. Among these patents are United States Patent No. 4,356,518 (the "'518 patent"), which claims the compound sertraline hydrochloride, and United States Patent No. 5,248,699 (the "'699 patent"), which claims a particular polymorphic form of sertraline hydrochloride.

In 1999, the predecessor to Ivax Pharmaceuticals, Inc. ("Ivax") notified Pfizer that it had filed an ANDA seeking FDA approval to market generic sertraline hydrochloride tablets. In that ANDA, Ivax filed a paragraph III certification with regard to the '518 patent, and thus sought approval for its generic product only beginning after the expiration of that patent, which (as adjusted by the FDA for six months due to Pfizer's performance of requested pediatric studies) will not occur until June 30, 2006. Ivax also filed a paragraph IV certification (claiming invalidity or non-infringement) with regard to the '699 patent. This latter patent will not expire until September 29, 2010, but Ivax's paragraph IV certification meant Ivax was seeking approval before that second patent expires.